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BEFORE THE

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UNITED STATES DEPARTMENT OF DEFENSE

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10 In the matter of: :

11 ARMED SERVICES :

12 EPIDEMIOLOGICAL BOARD :

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16 The above-entitled matter came on for

17 hearing pursuant to Notice before Dr. Lewis H.

18 Kuller, M.D. President and Colonel Michael R.

19 Peterson, USAF, BSC, Executive Secretary, at U. S.

20 Army Medical Research Institute of Infectious

21 Diseases Auditorium, Ft. Detrick, Maryland, in the

22 Dalrymple Conference Room on Thursday, July 7, 1994

23 at 8:00 o'clock a.m.

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P R O C E E D I N G S

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(Time Noted: 8:03 a.m.)

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DR. KULLER: Welcome, everybody, to
the Armed Forces Epidemiological Board meeting here
at Fort Detrick. If anybody has any problem
hearing, just give a yell and we'll try to make sure
everybody can hear.

16

We have a very interesting and very
expensive agenda. We have probably one of our
largest attendance in recent years at the meeting
and I think we'll have a very interesting meeting.

20

I'm Dr. Kuller and I'm the current
President of the Board. I'd like to welcome first a
few visitors who are with us today and some former
Board members and if they could just, if they're
here, just put up their hands so we can say hello.

1 Brigadier General Peter Hoffman, who
2 is the Commander of the Air Force Medical Operations
3 Agency. Welcome.

4 Rear Admiral Frank Young, who is the
5 Director of the Office of Emergency Preparedness,
6 National Disaster Medical Systems. He isn't here
7 yet.

8 Rear Admiral William Buckendorf, who
9 is the Assistant Chief, Operational Medicine.
10 Welcome. And Fleet Support.

11 Rear Admiral Dennis Wright, Medical
12 Officer, U.S. Marine Corp. He'll be here tomorrow.

13 Dr. James Zimble, who is the President
14 of the School of Medicine, Uniformed Services, who I
15 guess will be here later, if he's not here now. Oh,
16 there he is. Hi, welcome.

17 Dr. Florabel Mullick, who is the
18 Associate Director of the Armed Forces Institute of
19 Pathology. She's not here yet. Okay. They will be
20 with us.

21 And Major General Philip Russell.
22 They all will be with us during the next couple of
23 days and when they come in, we'll try to introduce
24 them.

1 We're really delighted today also to have
2 both former Board members and especially, for today
3 and tomorrow's discussion, both the history and
4 probably the brains of the Board in terms of
5 vaccines and infectious diseases with us today, and
6 it's going to be really very nice for them to come.

7 Bud Benenson, Bud. Dr. Frank Engley. Dr. Bill
8 Jordan. And especially Dr. Ted Woodward. Thanks
9 for coming.

10 We also today have a little bit of
11 difference in our meeting, we have two
12 representatives from the press who are here, and I
13 wonder if they could also show us -- Ms. Covina, is
14 she here yet?

15 MS. CANAVAN: Kanovin.

16 DR. KULLER: Did I mispronounce it? Sorry
17 about that.

18 MS. CANAVAN: That's all right.

19 DR. KULLER: That's the way they have it
20 written here. And Ms. Nelson. Is she here?
21 Welcome, and if we can be of any help during the
22 meetings, let us know.

23 And at that, I'm going to turn over the
24 meeting for a moment to Dr. Peterson, who will give

1 us some background about logistics and where we're
2 going.

3 COLONEL PETERSON: Thank you. Also, I'd
4 like to extend my welcome to everyone. Glad you
5 could make it to the meeting today and tomorrow.

6 Just a couple of administrative items. At
7 10:15, we'll try to gather the Board members all in
8 one place for a picture, so please don't everybody
9 head out the door at the same time. Board members
10 stick around and we'll try to get a picture as a
11 group at about 10:15.

12 Also, if you haven't been asked for two
13 dollars for the coffee, please see Ms. Ward at the
14 break and she'll get your money from you then.

15 Make sure if you have not signed in, please
16 print your name on the sign up sheet when you come
17 through the door, so we can keep a list of attendees
18 and before the day's over, we're going to try to
19 print that back out on a computer, so we'll take
20 everybody's name and phone number and where they
21 work for the future.

22 If there's anybody here who is attending
23 the dinner tonight that would like a vegetarian main
24 dish, please see Ms. Briggs, the young lady out at

1 the table from my office who took your name when you
2 signed in and we'll get that information to the
3 restaurant. That's just folks who want a vegetarian
4 main dish.

5 Directions to dinner after the meeting and
6 to the hotel from the dinner location, will be
7 printed out and will be available on the back table
8 here by the end of the day, so in case you can't
9 find your way around, you'll have the directions to
10 help you find where you need to go.

11 As usual, this session is being recorded
12 and you need to speak into the -- as close as you
13 can reasonably to the recording microphones, which
14 are these. And there aren't a lot of them on the
15 table and they should be able to pick up your voice
16 within a three, four or five person distance.

17 If you're going to make a comment from
18 those sitting around the table, please come closer
19 to the table rather than the second or third row
20 back.

21 The other microphones, the small ones on
22 the table, are the ones that are magnifying the
23 voice around the room and should be coming from
24 those speakers.

1 Can people hear me pretty well? It sounds
2 like they're coming through the speakers now. Okay.
3 You maybe need to be just a little closer. I think
4 it's coming through the speaker now. Okay. So be
5 sure to identify yourself by name and your
6 organization, if you're going to use the
7 microphones.

8 Restrooms are out the door and two your
9 left. There's two sets of restrooms. If you just
10 keep walking down the hall, both sets of restrooms
11 are in that direction.

12 There's also some pop machines and if
13 you're interested in anything like a breakfast item,
14 rolls and so forth, there's, I believe, some
15 enlisted folks here from the Institute, right around
16 the corner, who will be more than happy to take your
17 donation. There's a fund raiser for donuts and
18 cupcakes and things like that, so please feel free
19 to pitch in on that.

20 And then lunch right now is scheduled for
21 12:00 o'clock and I think probably the best thing to
22 do, expectations are that there's going to be a
23 large group of people coming down to the multi
24 purpose club down the street and we're going to kind

1 of all head down there, I think, as a ground at the
2 lunch time break at about 12:00 o'clock.

3 If there's any other questions that come up
4 in terms of an administrative nature, please feel
5 free to ask me and I'll turn it back over to Dr.
6 Kuller.

7 Colonel Takafuji, do you have anything you
8 want to add real quickly?

9 COLONEL TAKAFUJI: Good morning. I'd like
10 to extend a welcome to the Armed Forces
11 Epidemiological Board, as well as general officers
12 who are present here, and invited guests and all of
13 you ladies and gentlemen who took the extra effort
14 to come here, a long distance up here.

15 It's an honor for us to have you and to
16 host you up here for the AFEB meeting. You have
17 been here before, as many of you know, to discuss
18 issues in the past of concern to the military and a
19 lot has happened since your last meeting here, of
20 course.

21 We've gone through a war. We're going
22 through a period of down sizing and restructuring of
23 the military. We're also dealing with new threats,
24 emerging threats, that you will hear about probably

1 tomorrow in terms of how the old bio warfare
2 scenario is evolving.

3 And for many of you who are in a civilian
4 capacity for most of your time, you probably have
5 never had this type of exposure, so I think you'll
6 find it quite interesting and perhaps understand a
7 little bit more about why we are concerned about
8 some of these issues, but it looks like you're
9 headed for a very nice meeting.

10 Now unfortunately, this also coincides with
11 another large meeting going on in San Antonio that
12 General Lanoue has called on short notice to plan
13 the strategies for the future, so General Zajtchuk,
14 our new Commander, is not here, although he had
15 every intention of being here to meet with you.

16 And General Lanoue and his deputy, of
17 course, are also not here because of that very
18 reason, but they extend their very best regards to
19 you for a most productive meeting.

20 My staff and I are at your disposal. If
21 any of you need any assistance, either personal or
22 professional in nature, please do not hesitate to
23 call on myself or my secretary, Theresa, just down
24 the hall to the right. We'll be glad to assist you

1 and to help you with your stay here.

2 Again, welcome on behalf of the Command and
3 welcome on behalf of the Army Institute of
4 Infectious Diseases.

5 DR. KULLER: Thank you very much.

6 We're going to move ahead now with the
7 program and as usual, the first part of the program
8 will be the presentations by the preventive medicine
9 officers.

10 We're hoping that from now on, in the
11 future we'll get some update of what we've discussed
12 at the previous meetings, so that we can have some
13 continuity from meeting to meeting of issues that
14 occurred at previous meetings, issues that occurred
15 at previous meetings.

16 So I'm going to start out with Captain Berg
17 from the Navy.

18 CAPTAIN BERG: Good morning, my name is
19 Bill Berg and I will be presenting an update on
20 preventive medicine issues in the Navy as quickly as
21 we get the overheads up there.

22 We have not had anything terribly dramatic
23 since the last meeting of the Board, but there are
24 some things that we think will be of interest.

1 Next overhead, please.

2 At the last meeting, I gave you an update
3 on the studies in Desert Storm veterans,
4 Construction Battalion 24. We have refined these
5 figures and gone on to look at -- included the data
6 from Detachments 1124 in Atlanta and 624 in
7 Nashville.

8 Rather than rehash much of this, the
9 detailed statistical findings are in a handout up
10 front there. We were able to interview 154 out of
11 232 Desert Storm veterans for a total of 66 percent.

12 Next overhead, please.

13 And these are conclusions. This is a very
14 symptomatic group, there are an average of nine
15 symptoms per veteran. Most of the symptoms, as
16 reported by the veterans, have either stayed the
17 same or even gotten worse in the past year.

18 Surprisingly, about a third of them have
19 gotten better or gone away entirely. The most
20 notable one in this regard is diarrhea. The
21 symptoms still do not suggest any particular pattern
22 or illness.

23 This is quite compatible with the reports
24 from the Defense Science Board Task Force headed by

1 Dr. Letteburg and the NIH technology assessment.

2 The symptoms are not sufficiently severe to prevent
3 people from working.

4 On an average, 86 percent of the reservists
5 lost ten or fewer work days in the past year.

6 There's a caveat here. We don't have any
7 information about sick leave and for many of these
8 people, they have no sick leave. If they don't
9 work, they don't get paid.

10 The type and frequency of medical diagnoses
11 appear normal. 62 percent have no formal medical
12 diagnosis, but the ones that are available are a
13 potpourri of things that you might see in any
14 internal medicine clinic.

15 The average age for this group is 42, which
16 puts it about twelve years older than the average
17 active duty veteran in Desert Storm and about ten
18 years older than the average reservist or National
19 Guardsman. And, in fact, some of the individuals
20 are up in their 50s.

21 There have been two deaths, one in an auto
22 accident and one that appears to be an acute
23 cardiovascular episode of some type. Three
24 individuals carry a diagnosis of, quote, "Persian

1 Gulf Syndrome." No information from their
2 physicians as to why this diagnosis was given to
3 them.

4 And finally, post-traumatic stress disorder
5 has been very rarely seen in this group. I think
6 it's worth calling your attention to some of the
7 information that came out at the NIH technology
8 assessment, pointing out that the criteria for PTSD
9 that we now mostly use, are based upon the Vietnam
10 era veterans and those may need to be adjusted for
11 this group.

12 Next overhead, please.

13 We have also been involved in an episode of
14 diarrhea at Wherry Housing at Naval Air Station
15 Oceana, down in Virginia Beach. This is of interest
16 because we started out to look at in diarrhea and it
17 has subsequently gone on into other areas.

18 This first came to our attention in May in
19 a picture in the local paper, in which a resident of
20 Wherry Housing was holding up a glass of water
21 saying she and her family and neighbors had had
22 diarrhea for several weeks and it was due to the
23 water, because the water left a film in her mouth
24 and did not quench her thirst.

1 We went in to investigate this. This is
2 very old housing that is due to be torn down and
3 replaced. It is considered sub-standard and one of
4 the particular problems is that the sewer lines are
5 inadequate. They're too narrow by today's
6 standards and they tend to plug up, particularly
7 when people try to flush diapers down them. There
8 were three confirmed cases of shigella, all of whom
9 were in the same family. Otherwise we have no
10 micro-biological diagnosis.

11 By report, the diarrhea stops almost
12 immediately when they switched to bottled water and
13 resumes almost immediately when they switch back to
14 tap water.

15 We went in and interviewed the individuals.
16 Wherry Housing we divided into three areas, east,
17 central and west. Most of the initial reports came
18 from the east area. Overall we were able to
19 interview 43 of 64 apartments, for a total of about
20 67 percent. Wherry East, which is where the
21 initial reports came from, had a much higher
22 prevalence of self-reported diarrhea and related
23 symptoms. Interestingly, there was no
24 association with anyone in the family being in day

1 care and there was no association with how long they
2 had been in Wherry Housing.

3 We looked at the water, which was our
4 immediate concern, why we first jumped into this,
5 and there was no problem. Repeated measurements
6 indicated adequate levels of residual chlorine, both
7 at each end of the housing where the water came in,
8 and at the individual taps.

9 Fecal coliforms repeatedly were negative.
10 We also testes a little stream that runs along
11 behind the housing. That had a few coli iron and
12 other organisms, but basically did not appear to be
13 polluted.

14 Numerous tests for lead and copper were all
15 below the detectable limits, so we did not feel the
16 water was implicated. This is old plumbing and one
17 of the banes of the public work center is having to
18 go and make plumbing calls there.

19 The proportion of plumbing calls to Wherry
20 East is just the same as for the other two areas.
21 Many of these are for things such as a plugged up
22 sink. When we looked at specific evidence of
23 sewer outflow, such as the toilet overflowing and
24 flooding across the floor of the apartment, none of

1 the eight sewer calls came out of Wherry East.

2 We are working, at the moment
3 concentrating, trying to get the residents of Wherry
4 East to come in and give us a stool specimen, so we
5 can try and identify what organism, if any, is
6 causing this. This has been a bit of a problem
7 because they have not presented many stools.

8 Approximately ten have been submitted and
9 none of them have grown any bacterial pathogens or
10 had any protozoa identified.

11 So we are continuing to work on this,
12 although now this is generalized to complaints of
13 jet fuel in the tap water and/or the sewer system
14 and then more generally, into environmental toxins
15 not further defined. So I'm sure we will have a
16 follow up report of this one.

17 Next overhead, please.

18 In response to the request for follow up on
19 issues, one of the recurrent issues has been
20 pneumonia at Camp Pendleton, and there are two parts
21 of this. This is the plan for the 1994-1995
22 pneumonia season, as it is called out there at
23 Preventive Medicine Unit 5.

24 The key point, in accordance with the

1 recommendations of the Board, are that all recruits
2 will get pneumococcal vaccine starting in October
3 and continuing through April.

4 This is actually being pushed up a little
5 bit in order to -- for reasons which I'll get into
6 in the next slide, but the bottom line is that all
7 recruits will get pneumococcal vaccine at the very
8 beginning of their training.

9 The training is approximately eleven weeks,
10 so they should have an adequate time to have a good
11 antibody response before they move on up to Camp
12 Pendleton. Up at Camp Pendleton, all cases will be
13 admitted to the hospital and certain standard tests
14 will be done on this.

15 This sounds relatively straight forward,
16 but in the past, evaluation of this has been
17 complicated by a tendency to treat what has been
18 regarded as very minor pneumonia on an out patient
19 basis and this will allow some standardized
20 collection of data.

21 And finally, representatives of Preventive
22 Medicine Unit 5, led by Captain Ledbetter, in the
23 back, periodically will go up to Area 52, which is
24 where the infantry training is carried out and

1 inspect for such things as adequate air space and
2 head to foot berthing and so on.

3 We will let you know, probably in the
4 February meeting, what has come of this, but these
5 are the plans to prevent pneumonia up at Camp
6 Pendleton.

7 Next slide.

8 The other part of this is a study being
9 conducted by Commander Greg Gray, who is here and
10 who will be reporting on a Persian Gulf veteran
11 study that he will be conducting, but he is also
12 doing a study, prophylaxis study up at Camp
13 Pendleton.

14 And I'm just going to hit the merest
15 highlights of this. If you have additional
16 questions, he can answer them.

17 Basically, as the title indicates, this is
18 a three arm study, giving prophylaxis with
19 erythromycin benzathine penicillin and no
20 antibiotic in an attempt to see if this reduces the
21 incidents of pneumonia.

22 To refresh your memory, the timing is that
23 the recruits go to Marine Corps Recruit Depot in San
24 Diego for approximately eleven weeks. There are

1 then about two weeks on leave and then they go up to
2 Camp Pendleton for infantry training which lasts
3 about six weeks.

4 1,200 Marines will be enrolled, This was
5 the number that was determined to have an adequate
6 efficacy to demonstrate or an adequate statistical
7 power to demonstrate an efficacy of 75 percent. All
8 will be volunteers; 400 will get erythromycin and so
9 on.

10 Enrollment will be done in October and
11 December. The pneumococcal vaccine will be pushed
12 up a little bit so that everyone who gets enrolled
13 in the study will have had pneumococcal vaccine.

14 Approximately three years ago, there was
15 evidence of pneumococcal pneumonia. The more recent
16 years have not indicated that pneumococcal pneumonia
17 is particularly a problem. And, in any case, it was
18 felt more appropriate to try to prevent this than to
19 study it.

20 Several outcomes will be looked at. The
21 incidents of acute respiratory disease,
22 seroconversion to a variety of agents and then some
23 unique studies using large fans to collect air
24 samples on filters and test these for various

1 respiratory pathogens using PCR.

2 Next overhead, please.

3 And I'm going to go very briefly, basically
4 just show you the criteria and the organisms that
5 are going to be tested for. The criteria for acute
6 respiratory infection will be one or more of those
7 clinical findings.

8 The prophylaxis efficacy study, which is
9 the heart of this, can we give an antibiotic which
10 will reduce the incidents of pneumonia. We'll look
11 at seroconversion to streptococcus pyogenes,
12 chlamydia pneumonia strain twar and mycoplasma
13 pneumonia.

14 Some preliminary serological data from last
15 winter indicated that about 40 percent up in Area 42
16 seroconverted from mycoplasma pneumonia. And then
17 there's going to be looking at surveillance and
18 carrier and etiological studies, looking at a
19 variety of organisms.

20 Next overhead, please.

21 And I'll just let you look briefly at that.
22 Basically, the attempt is either by culture, or
23 more particularly by serology, to look for all of
24 the common respiratory pathogens.

1 Next overhead, please.

2 Turning from the West Coast to the Far
3 East, a few weeks ago Cobra Gold '94, the annual
4 exercise in Thailand finished up. Captain Ledbetter
5 was the preventive medicine officer there, using the
6 same technique that was first developed for
7 Operation Desert Storm.

8 Morbidity surveillance was in place and
9 indicated over all a very low prevalence of
10 morbidity. These are the nine most common diseases
11 that were reported and, at the end, we're trailing
12 off. In fact, sexually transmitted diseases are
13 perhaps included more for sentimental reasons than
14 anything else.

15 As you will recall, there are about ten
16 categories. These are very broad categories and the
17 idea is that if there is a blip in any of them, more
18 intensive survey logs can be put in place to
19 identify exactly what is causing this.

20 And in fact, what I have up there, Number 6
21 is heat injury, is actually heat and cold injury in
22 the formal categorization.

23 The first column is the total number of
24 individuals who had that particular problem. The

1 next column is the cumulative percent, based on the
2 average weekly population.

3 And so, for example, in the first row,
4 there were 357 individuals who had a dermatological
5 problem. The average population was -- well, you
6 can see it below the right-hand corner, 3,267
7 Marines, and so the cumulative percent is eleven
8 percent of the individuals had a dermatological
9 problem.

10 The third column is the lowest incidents
11 per week and then the fourth column is the highest
12 incidents per week. Overall, ranging from
13 dermatological down to sexually transmitted
14 diseases, there were very few diseases of any kind.

15 Dermatological was primarily fungi. G-I
16 was diarrhea, as you might expect. The majority of
17 orthopedic and surgery were trauma, particularly
18 from sports and general horsing around.

19 By report, there was a great deal of sexual
20 activity, but there was also a lot of condoms passed
21 out and this may account for the low rate of
22 sexually transmitted diseases.

23 Next overhead, please.

24 The forward deployable lab was deployed in

1 a trial basis and looked at the etiological agents
2 of diarrhea. Sixty specimens were submitted, which
3 represents approximately twenty of the G-I
4 complaints, thoroughly reasonably representative
5 from the most accessible battalion aid stations.

6 And you can see the figures up there of
7 interest. 54 percent of the cases were due to
8 campylobacter, either alone or with some other
9 agent. And of further interest and concern, about
10 75 percent of these were resistant to syrophloxogen
11 on sensitivity testing.

12 Now, clinically some of them seem to
13 respond to it and others either went away on their
14 own or we don't have much information on it. We're
15 just beginning to get into this data, so we don't
16 know how many of these 60 are refractory cases and
17 how many simply came in on the first day of their
18 diarrhea.

19 But the campylobacter resistant to
20 syrophloxogen is a finding of some concern. It's
21 not terribly surprising, at least to me, because
22 innoxicin is one of the early quinalones that's been
23 used in that part of the world for at least ten
24 years and there tends to be pan resistance to

1 quinalones.

2 Next overhead, please.

3 And continuing on, there were a very small
4 number of protozoan parasites causing diarrhea, a
5 serological elisa test for rotavirus was also used
6 and this picked up two cases of rotavirus.

7 Next.

8 Okay, you've all been reading in the paper
9 about the virus that ate my face and this sort of
10 stuff. And the infectious disease people, at least
11 in the Navy and nationally, have sort of been saying
12 well, this has been around all along, this is an
13 epidemic of media interest more so the streptococcal
14 disease.

15 The day before yesterday, the head of
16 Infectious Diseases at Naval Hospital Portsmouth
17 called me somewhat chagrined and said I have tallied
18 up our cases. We've had five since February.

19 And unfortunately, we have no background
20 information, so we don't know whether this is the
21 norm or an increase or even a decrease, but I
22 thought I would share them with you, particularly
23 because of the five there were two deaths.

24 The first one was an eight year old white

1 male dependent son who came in with a priogenic
2 streptococcal arthritis of his elbow, developed
3 sepsis and died within 12 hours. This was sera type
4 and was serra typed M1.

5 The next one was a 50 year old white female
6 dependent wife with insulin dependent diabetes, who
7 came in with streptococcal pneumonia and an empyema.
8 She recovered. Her serra type was untypeable.

9 The third case, also in February, was a 36
10 year old white female, activity duty individual who
11 was having some endocrinological abnormalities and
12 had an adrenalectomy.

13 About two days later, the wound was
14 infected and this turned out to be a severe case of
15 necrotizing fasciitis that required extensive
16 debreatment. Her strain also was untypeable.

17 Next overhead, please.

18 The fourth case, in April a 40 year old
19 female, active duty who had out patient liposuction
20 and came back two days later -- three days later
21 complaining of a wound infection.

22 This was extensive necrotizing fasciitis
23 and toxic shock syndrome with desquamation of her
24 fingertips and toes. She required extensive

1 debreatment and cosmetic procedures before she was
2 out of the woods.

3 And then finally this past weekend, a three
4 year old with secondary infected Chicken Pox, who
5 was admitted and died within eight hours.

6 The sixth case is only clinical. This was
7 an individual who had a vasectomy reversed and
8 clinically had a toxic shock syndrome. No organisms
9 could be recovered because the urologist pumped him
10 full of antibiotics before calling in the ID folks.

11 We have no idea whether this is the norm or
12 an increase or a decrease, but we are planning on
13 asking BuMed to send out a message to all of the
14 Navy hospitals, asking to specifically report cases
15 of streptococcal sepsis to us, so we can begin to
16 get a handle on what is going on.

17 And that is the situation in Navy
18 preventive medicine. Thank you.

19 DR. KULLER: Thank you very much, Captain
20 Berg. Are there questions for Captain Berg? Yes,
21 sir.

22 VOICE: Are we going to address some of
23 this later on or is this an appropriate time?

24 DR. KULLER: I think this would be an

1 appropriate time for specific questions about the
2 report.

3 VOICE: I was very impressed with the
4 overall level of activity that's going on and I
5 think it's quite, to me, evidence of very good work
6 being done, particularly this study on the etiology
7 of the agents at Pendleton, but I have to raise an
8 issue that I brought up before about the prophylaxis
9 study and particularly in relation to the fact that
10 we now have developed in this country the emergence
11 of what were resistant pneumococci.

12 It has been brought home to us in
13 Charlottesville because we made the decision that
14 every case of meningitis that we see where we
15 suspect pneumococcus, we're now treating with
16 achromycin.

17 We're now learning to take risks on
18 pneumonia, realizing that pneumonia can also kill
19 you, but then we have nothing else to use. We feel
20 we're particularly vulnerable for two reasons,
21 because Tennessee is close to us where they have a
22 fairly large outbreak and where in Charlottesville,
23 Virginia, we're seeing these strains now.

24 And so I am concerned about using

1 prophylaxis unless we know specifically what we are
2 doing, both in relation to the pneumococcus and
3 Group A streptococcus which, as of today, is not
4 resistant to penicillin, but we're learning, I
5 think, a bitter lesson that we have to pay a price
6 which in the case of pneumococcus, may be a very
7 large price.

8 So I would just say that that means careful
9 consideration before prophylaxis is given. I don't
10 think that that one instance is going to affect it
11 overall and probably, more important would be the
12 widespread use of betalactam in children in this
13 country in recent years to prevent odysmedan with
14 thousands and thousands of children that have been
15 on this, but each time we do it, we are going to pay
16 some price probably for it.

17 CAPTAIN BERG: I share your concern on
18 that, and that is why the studies are designed to be
19 very carefully monitored.

20 My particular concern also is with the
21 betalactams. However, this does not, multiple drug
22 resistant pneumococcus does not appear to be a
23 problem in the San Diego area, and particularly in
24 the recruit population that we're focusing on, which

1 has historically received Benzathine penicillin even
2 in San Diego to prevent streptococcal pharyngitis
3 and rheumatic fever for many years.

4 But we are -- I share your concern and this
5 is being watched very carefully. Commander Gray,
6 would you like to comment on that?

7 COMMANDER GRAY: I would just like to add
8 that we were concerned enough to talk to Dr. Barbara
9 Murray, who's an expert in sort of the state of
10 endocroviaal antibiotic resistance.

11 And her opinion was with the short duration
12 of treatment and the very dynamic population we see
13 in our training camps, that we would likely not be a
14 cause of national increased resistance.

15 Additionally, we have monitored strep
16 pyogenes resistance periodically over the years in
17 concert with the use of benzathine, and in the last
18 three years, oral erythromycin in those who are
19 penicillin resistant and we have not seen an
20 increase in antibiotic resistant among the islet, so
21 we are somewhat reassured by that.

22 DR. KULLER: Yes.

23 MS. YOUNG: I think the observations on the
24 Group A strep are very interesting from Portland. I

1 wonder what you might be able to do in terms of
2 establishing a baseline. It doesn't sound like most
3 of these were back to remake or sharing a
4 particularly common syndrome.

5 How are you thinking of approaching that?

6 CAPTAIN BERG: Most of them were back to
7 remake. Approximately -- I don't recall the exact
8 number, but I think at least four of them, the
9 organism was cultured from the blood.

10 This came up very quickly and Dr. Izarowitz
11 called me knowing that I was coming up here, so he
12 is digging through the cases to get more details on
13 these and the other ones. So that will be the
14 starting point and from there we will design some
15 reporting standards so that we can collect
16 comparable data from all of the hospitals.

17 DR. KULLER: What you said then is a plan
18 to do an epidemic -- epidemiological surveillance to
19 determine whether this is really an epidemic that's
20 now occurring --

21 CAPTAIN BERG: Correct.

22 DR. KULLER: -- or whether this is just
23 background. So it would be a systematic approach
24 rather than just poetic -- case histories?

1 CAPTAIN BERG: That's correct. This is the
2 infectious disease people saying this is not new,
3 we've seen severely streptococcal disease for years
4 and then, wait a minute we have had five cases since
5 February, maybe we do have a problem here.

6 So we're just -- this is the very beginning
7 and, as you say, we're going to start looking at
8 this in a systematic fashion.

9 VOICE: In view of the problem with HIV --
10 I wonder if you're doing any surveillance for HIV --

11 CAPTAIN BERG: Yes, by Navy policy everyone
12 who has a sexually transmitted disease gets tested
13 for HIV at the time, because we take the sexually
14 transmitted disease as a marker of someone who's at
15 risk and then further on, particularly in an
16 environment like this.

17 VOICE: But no general testing.

18 CAPTAIN BERG: I'm sorry, everyone on
19 active duty in the deployable forces is tested
20 yearly.

21 VOICE: Okay.

22 DR. KULLER: Could those who ask a question
23 give their name, so our recorder over there is, I
24 noticed is having some effort finding out who's

1 speaking. Thank you.

2 Any other questions of Dr. Berg?

3 Thank you very much for a good report.

4 CAPTAIN BERG: Thank you.

5 DR. KULLER: Colonel Erdtmann. Okay,
6 Colonel Tomlinson is going to be talking for the
7 Army.

8 COLONEL TOMLINSON: Yes, I'm Pitt
9 Tomlinson. Colonel Erdtmann decided -- he found
10 out at the last minute he would be unable to be here
11 this morning. He does hope to get here later this
12 afternoon and will definitely be here by supper
13 tonight and he will be here through tomorrow.

14 In addition to his title as Preventive
15 Medicine Consultant, he is a Deputy Chief of the
16 Medical Corps and that takes probably an equal
17 amount of his time now as his preventive medicine
18 duties.

19 The Army Medical Department, as we've
20 mentioned before, is reorganizing, but have the
21 first overhead. Our office at the Pentagon, which
22 now has a staff of twelve, will be reduced to two
23 individuals. There will be one physician and one
24 Medical Service Corps officer.

1 The new Medical Command Headquarters is
2 located at Fort Sam Houston in San Antonio, and at
3 the Headquarters, we will have seven preventive
4 medicine officers assigned there.

5 If you will look to your far right, that is
6 the new, recently approved Preventive Medicine
7 Center. And below that are the support agencies.
8 There are three in the United States, one in Japan
9 and one in Germany.

10 We'll go to the next slide and I'll show
11 you a wire diagram of the Preventive Medicine
12 Center. The name has been selected, it will be the
13 U.S. Army Center for Health Promotion and Preventive
14 Medicine, and it will be located at Aberdeen Proving
15 Ground, which is north of Baltimore.

16 The Center will have a Brigadier General
17 Commander and you can see the various divisions, as
18 you go down through the third level, clinical
19 preventive medicine, the division of health
20 promotion, division of epidemiology and
21 surveillance. This will be equivalent to our
22 preventive medicine group at WRAIR now, but it will
23 be expanded further than that.

24 There'll be an environmental health

1 division; a division of laboratory sciences,
2 primarily toxicology, environmental type chemistry
3 laboratory; a division of occupational health; field
4 preventive medicine, which does many of our studies
5 and investigations.

6 And again, the support agencies, CONUS,
7 within the United States and OCONUS, outside of the
8 United States. Provisionally, that will be
9 established on the first of August of this year.

10 There will be a one or two or three year
11 transition period in which changes are made, the
12 facility is renovated for the staff, and for the
13 assignment of personnel, both civilian and military
14 to that group.

15 Something has already been said this
16 morning about the unexplained illnesses that have
17 been seen in Persian War Gulf veterans. We'll go to
18 the next line.

19 The Department of Defense Health Affairs
20 has initiated a comprehensive clinical evaluation
21 program. This is a medical work up that is being
22 offered to any Persian Gulf war veteran with
23 symptoms possibly related to service in Southwest
24 Asia. It also is including family members of

1 those veterans.

2 The slides I will show you are applicable
3 to the Navy Air Force as well as to the Army. This
4 is a triservice project and I just want to give you
5 an overview of it, so that you can see what is being
6 undertaken in this area.

7 Every veteran or family member will be
8 offered an evaluation at the local hospital, the on
9 post hospital. That will be the phase one
10 evaluation and at that time, the individual will be
11 entered into the registry as being a bona fide
12 patient and at that level.

13 There will be a routine history and
14 physical examination, routine laboratory such as
15 CBC, urinalysis, blood chemistries, chest x-ray, and
16 any other tests which are indicated by the patient's
17 signs or symptoms.

18 If the complaint can be taken care of, if
19 the patient can be satisfied, then the patient will
20 be treated and returned to duty, returned home and
21 that would be the end of it.

22 However, if there's any question remaining
23 in the minds of the physician or if there's any
24 question remaining in the mind of the patient that

1 these symptoms may in some way be related to service
2 in Southwest Asia, the patient goes on to phase two.

3 Next overhead.

4 Phase two is more extensive. It will be
5 done at one of thirteen regional Medical Centers,
6 military Medical Centers. This is a triservice
7 program.

8 Some of the regions have Air Force, some
9 Navy, some Army Medical Centers as a regional
10 Medical Center, so members of the various services
11 may all be seen in a Navy hospital or in an Army
12 hospital or Air Force for that work up.

13 The next slide, please, shows what this
14 work up consists of. As you can see, there are a
15 multitude of tests to be done. This phase is
16 estimated to take about two weeks. It can be done
17 either on an in patient or an out patient basis.

18 In addition to those tests, which must be
19 done, there are certain consultations that must be
20 done, including the neurology, infectious disease,
21 dental and a psychiatry/psychology consultation.

22 There are many tests that are going to be
23 done.

24 Now, some of the psychiatric and neuro-

1 psychological tests have been moved into phase
2 three, but basically this is phase two, which will
3 be done at the Medical Center.

4 If at the end of this investigation,
5 there's no explanation for all of the symptoms of
6 the patient, if no definite diagnosis has been
7 arrived at, if the patient is not satisfied with the
8 diagnosis, or if the physician cannot explain it
9 fully, the patient goes on to phase three which is
10 also done at the Medical Center.

11 If we could have the next slide?

12 So phase three moves into additional
13 testing, additional consultations, as well as a
14 fairly extensive questionnaire, trying to gather
15 some information on the possibility of multiple
16 chemical sensitivity; also trying to determine if
17 the use of the nerve agent antidote Pyridostigmine
18 Bromide might in some way be related.

19 Next, over here, in phase three the
20 patients will be done more on a case by case basis.

21 Depending on the remaining complaints, these
22 various tests will be done.

23 At the end of phase three, if all of the
24 symptoms have not been adequately explained to the

1 physician or to the patient, then the patient's
2 medical record will be reviewed by an expert panel,
3 which is to be put together by Health Affairs, to
4 review the records of all those individuals who
5 progress through phase three and never get
6 diagnosed.

7 And at that time, either -- perhaps there
8 will be some type of a provisional definition or
9 case definition. So far all attempts to come up
10 with a case definition have failed and it may be at
11 the end, we still won't have the answer, but this is
12 just to let you know the process that these
13 individuals are going through.

14 First, there are about 350 individuals from
15 the three services who are to have these
16 examinations completed by the first of October.
17 They have already started. These are individuals we
18 already had registered, we knew had complaints and
19 had already been worked up previously. They all go
20 through this again.

21 Also, the new patients are registering
22 daily and coming into the system. Those
23 individuals, anyone who comes in with a complaint,
24 goes through this same process now. As you can see,

1 it's an extremely large program. It is putting a
2 heavy work load on the community hospitals, on the
3 Medical Centers and it is underway now.

4 Also, similar type work up is being done at
5 the VA. This program at the active hospitals is
6 there for not only active duty, but for anyone in
7 the active Reserve or active National Guard.
8 Individuals who are completely separated from
9 service or individuals in the Reserve or Guard who
10 wish to, may go to the VA for some of the work up.

11 That's the end of the slides. I did have
12 an update I wanted to give. Number one would be
13 from the injury subgroup. At the last meeting of
14 the AFEB, the Board voted to form an injury subgroup
15 to meet with the regular AFEB injury committee,
16 which is Doctors Hansen, Perrotta and Carol.

17 Dr. Bruce Jones, who heads the DOD injury
18 surveillance and prevention work group, has
19 nominated eight individuals for the subgroup and
20 their names will be submitted to the Board later
21 today.

22 Of interest, Dr. Jones and his group at the
23 U.S. Army Institute Research for Environmental
24 Medicine, which is at Natick, Massachusetts, just

1 this month published an article in the American
2 Journal of Preventive Medicine which links smoking
3 an increased risk of injury, and it has received
4 national attention.

5 This is from Tuesday's Boston Globe, an
6 article, Smokers Found Prone to Injury, and this has
7 been picked up by the national media. It's been on
8 CNN radio the day before yesterday. I just happened
9 to hear it.

10 Dr. Jones is here and will be here. He's
11 not presenting at this meeting, but if there are any
12 questions about his injury control working group or
13 study, Bruce would you stand up just to identify
14 yourself? I think most of you know him. Thank you.

15 Also another report, Dr. Ben Denyager
16 headed up a group which looked at tropical medicine
17 training in the military services, and he gave a
18 report at the meeting at Fort Bragg.

19 That group has made several recommendations
20 to the Surgeon General just the week before last,
21 and those recommendations concerning tropical
22 medicine training are that there will be
23 consolidation of the Navy and Army tropical medical
24 courses into a DOD advanced course, which

1 will be at USAS, and will be either under the
2 auspices of the Army or the Navy.

3 There will be a conversion of the Air Force
4 global medicine course into the DOD basic course.
5 The services will formalize tropical medical
6 training requirements for health care providers and
7 physicians. The Army plans to make tropical
8 medicine training an additional skill identifier.

9 And that group will continue to work and is
10 going to be meeting again in September. Colonel
11 Denyager is here and if you should have any
12 questions for him -- the last time he was here and
13 up until yesterday, he was Lieutenant Colonel
14 Denyager, but he is now Colonel.

15 Colonel Denyager, would you stand up so
16 everyone can see you? In case you have questions
17 about that.

18 (Applause.)

19 COLONEL TOMLINSON: And the final thing I
20 wanted to mention was something that came up just
21 two days ago. We learned that there are two
22 probable cases of Hemorrhagic Fever in Korea; both
23 females, both in the same company of the Second
24 Infantry Division.

1 One of the patients died. The other is
2 alive, doing well and robofiron therapy has been
3 started. We have not confirmed those. Blood
4 specimens as well as tissue samples from autopsy are
5 being sent here to USAMRIID for confirmation.

6 And we're tentatively planning to do a sera
7 survey of the company, which would be about 200
8 soldiers or possibly the battalion, which may be six
9 or 800 soldiers for KHF and possibly other
10 infectious diseases. That will be done here at
11 USAMRIID.

12 Colonel Takafuji has -- maintains
13 operatives in Korea, always looking for research
14 opportunities and they were fortunate that one of
15 the individuals was there and our preventive
16 medicine people have already begun work on this. So
17 next meeting, we should have a report on the outcome
18 of that.

19 And that's all I have. Are there any
20 questions?

21 DR. KULLER: Any questions of Colonel
22 Tomlinson? Yes.

23 DR. GWALTNEY: I'd like to make a comment.
24 As far as I know the history of American medicine,

1 I don't think there has ever been such a shameful
2 waste of resources as is being described in this
3 study that you described on the post Gulf war.

4 It's not based on any reasonable scientific
5 approach, as we understand science in this country,
6 number one. But worst of all, it is going to then
7 create anxiety and concern in thousand of innocent
8 victims of a misguided approach.

9 And I can imagine what young children in
10 these families hauled in to these medical
11 institutions by the government of the United States,
12 the fear it's going to create in their minds of some
13 disease that's affected their families and
14 themselves and I'm utterly opposed to it. Gwaltney,
15 University of Charlottesville.

16 DR. HANSEN: Dr. Hansen. I concur entirely
17 and I really think that we should do something to
18 change the course of events that we are seeing here,
19 that continue to evolve and explode. I believe this
20 is a politically incompetently handled matter.

21 COLONEL TOMLINSON: Thank you. This is an
22 Advisory Board to the Office of the Secretary of
23 Defense for Health Affairs, and I assume that these
24 comments will be forwarded to Health Affairs.

1 DR. KULLER: Yes. They were not aimed at
2 you, by the way, I assure you.

3 COLONEL TOMLINSON: Sir?

4 DR. KULLER: I said they were not aimed at
5 you personally.

6 COLONEL TOMLINSON: Yes, sir, and I have no
7 comment.

8 (Laughter.)

9 DR. ASCHER: No name. I was likewise very
10 surprised in the popular press when they had the
11 Veterans Administration misquoted as saying all of
12 these individuals should be diagnosed and
13 compensated almost by definition.

14 I don't know what defines a conflict of
15 interest, but to me that seems like a conflict of
16 interest and depending on what the view of the VA
17 is, --

18 COLONEL TOMLINSON: I'll turn it over to
19 the Air Force.

20 (Laughter.)

21 GENERAL HOFFMAN: If there's such a thing
22 as walking into a live fire zone, this is probably
23 it.

24 My name is Dr. Peter Hoffman and I'm from

1 the Office of the Surgeon General of the United
2 States Air Force, and I have participated in
3 watching the program be put together to try to
4 respond to what we perceive as a customer need from
5 our patients, our veterans, many of whom were still
6 on active duty that served in the Persian Gulf.

7 This entire program has been voluntary,
8 first of all. No one has been called, no one has
9 been brought, no one has been ordered to go anyplace
10 to have anything done.

11 The pressure that has occurred in the
12 Department, and this is a very delicate sort of
13 balance about how one responds to this, is the
14 perception in the Department, the perception
15 sometimes in the press and the perception from the
16 patients that the Department of Defense is either
17 not interested, is trying to conceal something,
18 lacks the professional expertise to evaluate the
19 patients or any number of continuing other potential
20 explanations or excuses for failure to respond to
21 the patients.

22 The dilemma that's created is the political
23 dilemma when, before the Congress of the United
24 States of America, the person responsible for health

1 in the Department of Defense testified that we've
2 examined the patients, we've done all the things
3 that we medically know how to do.

4 The NIH consensus there, when everybody
5 else has not been able to reach a case definition or
6 any particular recommendation about anything special
7 to do with this population of patients, and that we
8 have no clear explanation for these unexplained
9 symptoms.

10 And that's immediately followed by a quite
11 sincere parade of veterans that talk about their
12 illnesses and their disabilities and the
13 Department's ineffectual ability to listen to them
14 or to respond to them.

15 And that is the dilemma and the pressure on
16 the Department has primarily come from the Hill,
17 from a number of elected representatives and it has
18 gotten louder and louder and louder. It has gotten
19 to the point now where Congress is, in fact, talking
20 about compensating people for something that we have
21 yet to describe.

22 The veterans, the Department of Veterans
23 Affairs has had something of a standard approach to
24 try to evaluate these patients. And what the

1 Department of Defense set about doing was to try to
2 harmonize the Department's efforts with the
3 evaluation methodology used by the Veterans
4 Administration.

5 There are really two primary goals in the -
6 - or sort of two medical goals and then this third
7 goal of being responsive. Let me just sort of give
8 -- the first goal is being the responsive goal, to
9 deal with what the veterans community and our
10 elected representatives feel is a lack of
11 responsiveness.

12 So we have tried to put into place in the
13 Department of Defense an organized, systematic way
14 where anyone who feels that they need to be
15 evaluated, can gain access to evaluation.

16 Now, in terms of the evaluation, there are
17 really two medical intentions in the evaluation.
18 The first intention is really to try to use the
19 standard diagnostic techniques that we know and
20 understand to, in fact, see if we can arrive at no
21 explanations for the patient's complaints, existing,
22 standard, codeable, if necessary treatable, and if
23 necessary compensatable illnesses.

24 The intention of the protocol is really, if

1 you look at the first 350 patients who were on the
2 registry prior, who had self identified, self
3 identified, prior to 1 June, is to distill from that
4 group, if there is anything to be distilled, at the
5 end of the process the small number of patients who
6 still have an unexplained illness despite a complete
7 medical evaluation as thorough as we know how to do.

8 It would then be that group of patients
9 that would then -- the Department would be guided by
10 the expert civilian's scientific advice that they
11 have attempted to get and are getting in the future
12 about how that group could be further evaluated to
13 determine if there is an explanation of their
14 symptoms.

15 DR. GWALTNEY: Could I ask why the families
16 being included?

17 GENERAL HOFFMAN: Well, there was a lot of
18 debate about the issue of the families. The reason
19 the families have been included is in response --

20 My opinion is, the families have been
21 included in response to what we have heard in terms
22 of Congressional testimony, that the veterans
23 themselves have said that before I went away, I and
24 my family were one. Now I have returned and I am

1 ill and my family is ill and somehow what has
2 happened to me, is happening to them.

3 Now, the families are only included in the
4 permissive sense that if a veteran wants to bring
5 forth a family member at the initial phase of the
6 examination to be examined, then we offer that to
7 the veteran. We are in no sense attempting to
8 attract anyone.

9 What we are attempting to do, is we are
10 attempting to appear what we have always wanted to
11 appear, and that was responsive to the needs of the
12 veterans.

13 DR. GWALTNEY: Could I make one more
14 comment, please? Gwaltney of Charlottesville. I do
15 want to say that my remarks are made in the context
16 of trying to help the individuals who had these
17 complaints.

18 GENERAL HOFFMAN: Yes, sir.

19 DR. GWALTNEY: And I believe sincerely they
20 had these complaints, that they feel these different
21 things that they complain of.

22 And secondly, to continue to maintain the
23 efficiency of the Armed Services, which is what I
24 understand my responsibility is on serving on this

1 Board, both of these.

2 So I don't want to leave the impression
3 that I don't think this is a problem for the people
4 involved, I think they perceive it as a real
5 problem, but I don't think we can serve their needs
6 by doing things which we know from our scientific
7 expertise is not the right way to proceed.

8 And I particularly am concerned about
9 involving the families, creating this unnecessary
10 concern and anxiety in these individuals, when
11 there's no medical evidence at all to suggest they
12 have contracted some kind of contagious process,
13 which is wholly conceived out of some non scientific
14 kind of thought process by people not qualified to
15 make those decisions.

16 GENERAL HOFFMAN: Well, Dr. Gwaltney, you
17 know, I think your concerns are valid and they are
18 shared by the people that have been involved in
19 putting this together.

20 If it is a point, counterpoint discussion -
21 - and by the way, there was a lot of discussion
22 about the inclusion of family members and the pros
23 and cons for that.

24 The decision -- the counterpoint is what we

1 say to the veteran, what we say to the veteran's
2 Congressman who says my constituent's family is sick
3 and they are sick because the veteran is sick. and
4 the veteran is sick because he served and you
5 refuse, refuse to look at the patient. You
6 refuse to look at their family when they identified
7 to you that the family is sick.

8 So we attempt to -- we are not attempting
9 to establish a value judgment, we are attempting to
10 be responsive to the needs of our beneficiaries and
11 responsive to our political leadership for whom we
12 work.

13 Yes, sir.

14 DR. BUCKENDORF: I agree with what has
15 been said. I think there's a place early on, for
16 psychological behavioral modification or whatever is
17 the proper terminology of this sort, as most of us
18 know it is, by and large, a psychological problem,
19 anxiety reaction of experts being brought in early,
20 rather than going through these three tiers of
21 evaluation. Is an early on time a time for this to
22 be done?

23 GENERAL HOFFMAN: Essentially, phase one is
24 a medical examination similar -- it was originally

1 similar to an induction physical or commissioning
2 physical, that sort of thing; a general history and
3 a general physical.

4 If that does not -- at each step, we are
5 attempting to explain the patient's complaints. And
6 by the way, at each step we are successful in
7 explaining an ever increasing number of the
8 patient's complaints with no diagnosis.

9 It is at the second step, it is at the
10 first referral step, that the psychological
11 evaluation is done and the psychological evaluation
12 is done with a focus on post traumatic, on stress,
13 anxiety and evaluating those sorts of things that
14 you just spoke about.

15 Yes, sir.

16 DR. ASCHER: Early on in the discussion, we
17 heard some interesting data a couple of years ago
18 with respect to some of the control groups that were
19 studied and I'm wondering if you lost sight of that
20 issue.

21 We heard at one point that for deployed and
22 non deployed Reservists that the frequency of his
23 complaint is approximately similar.

24 GENERAL HOFFMAN: There's a study out that

1 was recently released that suggests that data may
2 still be valid.

3 DR. ASCHER: And that in addition, these
4 complaints would be served as a baseline for the
5 population. And also the issue that the Reservists
6 have higher rates of these, it would seem to me that
7 you need to have a social component of your
8 evaluation, particularly with regard to access to
9 health care and other things.

10 As an active Reservist, I spoke to the
11 Board before about the fact that if you put more of
12 your force in the Reserve component who do not have
13 health benefits during their normal life, who are
14 then deployed and come back and hit the street with
15 no health benefits, one of the things that they're
16 going to access through this mechanism is health
17 benefits.

18 And it seems to me that we have a societal
19 issue and a lot of this would be taken care of at
20 some level if you included health benefits for some
21 period of time after deployment and I think we've
22 learned this after the fact, but I would certainly
23 hope you wouldn't lose sight of the control group
24 for this problem.

1 It will be a major contribution to our
2 understanding of this whole complex chronic fatigue
3 and everything else if you could get baseline in a
4 population of people who've been deployed, who do
5 not complain, who were not deployed in the same
6 situation and tell us what fatigue, rash, diarrhea
7 and all of these other things and I think you'll
8 find that they're all the same.

9 GENERAL HOFFMAN: My last commercial and
10 perhaps we picked a very, very controversial subject
11 to work this issue on, I'd like to point out that
12 the Department of Defense, the Office of the
13 Assistant Secretary of Defense for Health Affairs
14 and the three Surgeon Generals over the last year or
15 so, have really tried to position and reorganize the
16 way health care, peace time health care is delivered
17 in the Continental United States in our managed care
18 program, which is called Tri-care, where the country
19 is divided up into twelve Tri-care regions with a
20 tertiary GME medical facility being the referral
21 facility for each of those regions.

22 Interestingly enough, the approach to the
23 Gulf War illness problem is the first example of a
24 peace time health care issue, which is being worked

1 on the basis of tri-care, on the basis of the lead
2 agents, without regard to service or uniform.

3 And the evaluation effort, in terms of the
4 ability to collect up the people, to contact the
5 people, to offer the people, if they want, further
6 evaluations and then to deliver those evaluations
7 seems to be going quite well.

8 Thank you very much.

9 DR. KULLER: I think we'll move on and
10 we'll certainly get back to this later in the day,
11 I'm sure and early in the afternoon.

12 We'll hear from the Air Force now, Colonel
13 Parkinson.

14 COLONEL PARKINSON: If I could have the
15 first slide, please.

16 First of all, let me just give me sincere
17 personal thanks to General Hoffman, who's pinch
18 hitting for General Sloan today. I'm not sure he'll
19 ever do it again.

20 (Laughter.)

21 COLONEL PARKINSON: But he actually did
22 come in from leave to go through this just a few
23 minutes ago, but with all due respect I want to also
24 thank Colonel Tomlinson for explaining the

1 comprehensive clinical evaluation protocol.

2 I'd be less than candid if I did not say
3 that it has taken a considerable amount of the
4 preventive medicine officers and our colleagues'
5 time in the last three to four months.

6 But more importantly, perhaps, and I think
7 this is a positive outcome of this effort, is the
8 notion that Dr. Joseph and others, even in the three
9 Surgeon General's offices, we thought for a long
10 time that perhaps we needed a more systematic
11 approach to pre-deployment, during deployment and
12 post deployment surveillance.

13 Hopefully, something that is rational, that
14 is targeted, that is high risk group specific, that
15 meets the criteria for good screening programs that
16 we'd apply in any public health department, and for
17 that reason, the Gulf War experience is kicking off
18 a more, let's say a more proactive stance.

19 We'll be working on some types of efforts
20 over the next three to four months also on the
21 flight officer working group that is chaired by Dr.
22 Martin at DOD Health Affairs.

23 To touch really briefly on a couple of
24 other things, the Put Prevention into Practice

1 campaign, we were notified last week that August
2 3rd, the Public Health Service will release the Put
3 Prevention into Practice campaign.

4 For those of you who don't know, this is a
5 series of provider, clinic and patient materials
6 which are designed and have been shown to be
7 effective in increasing the utilization of clinical
8 preventive services.

9 That is screening, counseling,
10 immunizations shown to be effective in reducing
11 premature morbidity and mortality, largely based on
12 the 1989 and now the newly revised 1994 Guide to
13 Clinical Preventive Services.

14 August 3rd, Secretary Shalala will be
15 releasing the campaign in all three, Air Force, Army
16 and Navy Surgeon Generals, are being formally
17 invited to participate in the release as kind of as
18 the heads of three major health care systems in the
19 United States.

20 The Office of Prevention and Health
21 Services Assessment, OPHSA as we call it in San
22 Antonio, I mentioned before that we will be serving
23 as the host for triservice Put Prevention into
24 Practice implementation meeting.

1 General Hoffman has recently signed a
2 letter inviting the flag officers of the other
3 services to nominate several members of the Army and
4 the Navy for a working group that we hope to hold
5 early August, probably August 8th and 9th to plan
6 this conference, to look at the specific challenges,
7 the barriers and the promise of increasing
8 preventive services in the three military services.

9 So we're looking very much forward to that.

10 Because you'll be hearing considerable
11 amount from Air Force blue suiters today on some of
12 our activities of the last four months, you'll be
13 hearing about OPHSA, a birth defects investigation
14 related to concerns of Gulf War veterans at Robbins
15 Air Force Base in Georgia, and evaluation of our
16 lead screening programs in the Air Force.

17 This is a very controversial area
18 increasingly in the civilian sector and I think you
19 will find it equally so in the military. And
20 finally, I'll be reviewing with you some of the
21 activities related to our fitness program, which has
22 been quite dramatic in the last three to four
23 months.

24 I did however think I would take this

1 opportunity, given -- next slide -- the increased
2 emphasis on HIV and AIDS education by the Clinton
3 Administration, to talk a little bit about our HIV
4 train the trainer effort, which just completed its
5 annual course in San Antonio.

6 Since the initiation of HIV program in
7 1986, the Air Force has had about 1,100 active duty
8 members identified over that period of time. We
9 currently have about 140 active duty members who are
10 HIV infected. The majority of individuals, once
11 they reach Walter Reed stages, five or six basically
12 are on TDRL status, which is temporary duty retired
13 list, but essentially we have about 140 at the
14 moment.

15 Next. Over time, the number of individuals
16 we've identified, of course, the big surge in the
17 initial total force screened back in '88 -- '87,
18 '88, identified a large number, a relative large
19 number. The rates in the Air Force have always been
20 relatively low and a half to a third of what they've
21 been in the other two services.

22 We're now identifying about 40 new Air
23 Force HIV infected members per year. Our incidence
24 rate is about point zero six per thousand members

1 per year.

2 Next. However, we continue to maintain a
3 high level of interest in HIV/AIDS and, to a large
4 degree, health behavior education in the Air Force.

5 Most recently, as you may be aware, Ms.
6 Christine Gebby, on the President's order, initiated
7 a Federal HIV/AIDS education initiative, looking at
8 not only personal -- decreasing personal risk of
9 disease acquisition, but also at work place policies
10 in the Federal sector, non discrimination, the
11 notion of how one does and does not get HIV/AIDS.

12 That effort was kicked off last year at
13 World AIDS Day and has been working its way through
14 the Department of Defense in terms of implementation
15 strategy.

16 Ms. Gebby most recently was in San Antonio
17 and had a presentation involving the Air Force's HIV
18 Train the Trainer course and I thought I'd share
19 with you a little bit about the Air Force's approach
20 of how we hope to implement this initiative.

21 Next. We're a little bit different in the
22 Air Force in the sense that we use a -- these flags
23 are in the way -- I'll do the ambidextrous
24 telephonic transmission here.

1 The Air Force is a little different in that
2 we tend to use inter-disciplinary teams at the base
3 level and provide centralized training once a year
4 to individuals at Wilford Hall Medical Center in San
5 Antonio.

6 The team typically consists of the HIV
7 designated position on base, as well as our Military
8 Public Health Officers, who are either nurses with
9 MPH training or Veterinarians likewise, with Public
10 Health training, who really serve as the hub of the
11 spoke on the base for HIV education efforts.

12 The program effectiveness, efficacy, is
13 measured by Wilford Hall through periodic surveys of
14 individuals who take the course, and we also get
15 some information concerning the audiences.

16 Under the President's HIV/AIDS initiative,
17 it has been -- basically the emphasis will be on the
18 civilian work force because since '86 - '87, we've
19 had in place other directives that require active
20 duty education efforts, so it will be a
21 comprehensive force effort.

22 However, it will focus a little bit more on
23 civilians initially, particularly civilian
24 supervisors as directed by the President's

1 initiative.

2 Next. Just to show you again that what
3 we're doing is, we're trying to elevate this course
4 within the list of courses that the Surgeon
5 General's office sponsors, so that we can ensure an
6 ongoing through put of members at the base level to
7 update them on the epidemiology of HIV/AIDS and the
8 latest techniques for communicating risk information
9 and policy changes, as they may evolve within DOD
10 and the United States Air Force.

11 Next. We had the notion that HIV and AIDS
12 education and the health risk behavior education
13 generally is an ongoing process. It's not a one
14 shot deal.

15 We increasingly see the need to have, not
16 only medical personnel involved, but also people
17 from our JAG or legal office, people from the
18 personnel office, people from the Chaplain's office.
19 It really is something that everybody at the base
20 level needs to be involved in.

21 Next. I don't need to read these to you,
22 but basically to show that we have a comprehensive
23 list of learning objectives for the course.

24 Next. And that we use a variety of

1 resources. At a typical base, we encourage our
2 Military Public Health Officers and HIV designated
3 providers to use the resources in the local
4 community, whether that be the Red Cross, whether it
5 be church or community groups, to support our
6 efforts.

7 What we find is that we just don't, as a
8 relatively small community in a larger community,
9 have all the resources to do the program as well as
10 we'd like and, therefore, what we try to do is get
11 everybody involved.

12 As you can see, the emphasis on work place
13 policies is something that is going to be increased
14 and has been already increased in this past year's
15 course and in future courses.

16 Next. We use a variety of formats, we try
17 to get away from the lecture format and the
18 presentation. We actually have, if we have dentists
19 and nurses and physicians and others involved in the
20 course, we try to get them to act as a team, to put
21 together presentations as they would, at the base
22 theater.

23 And also to take typical questions from
24 line commanders, supervisors, civilian supervisors

1 and HIV infected individuals, et cetera.

2 Next. And that's it. Well, as I said, I
3 tried to be brief. I'll take any questions, but
4 you'll hear a lot more about our activities over the
5 next -- this morning and this afternoon.

6 Thank you.

7 DR. KULLER: Any questions for Colonel
8 Parkinson?

9 Thank you very much.

10 Commander Unga, from the U. S. Coast Guard.

11 COMMANDER UNGS: Good morning. I did have
12 a presentation, but it was focused on the Haitian
13 situation and events, essentially, have overtaken
14 the slides I'd prepared and given to the flag brief
15 and the Commandant, so I'm going to give part of the
16 content from the top of my head, but the handouts I
17 had would be partly outdated and therefore
18 incorrect.

19 First, a brief introduction of the Coast
20 Guard. Some of you may not be highly familiar with
21 it. It is one of the Armed Services, though unlike
22 the other four Armed Services, it's under the
23 Department of Transportation.

24 But like our sister DOD Services, it has

1 some similarities in missions, such as the military
2 arena, but also has a large mission involvement with
3 humanitarian services and kind of law enforcement
4 services, such as enforcement of laws and treaties.

5 Myself, from the Office of Operational
6 Medicine, which is under the Office of Health and
7 Safety. The Coast Guard being a small service,
8 roughly 38,000 active duty, everything gets
9 compressed down. Our numbers are quite small
10 compared to our DOD sister services, so I end up
11 wearing many hats.

12 Let me give you a little brief on the
13 Haitian situation insofar as the Public Health and
14 Communicable Disease aspects.

15 The Haitian operations are part of what we
16 call alien migrant interdiction operations or AMIO.

17 Alien migrants is the State Department term for
18 these people such as the Haitians. That's the
19 official term that we use and that's to distinguish
20 between refugees.

21 AMIO operations for the Coast Guard's been
22 going on for some time, at least into the early 80s.

23 To date there have been -- the numbers are rapidly
24 changing. There's 75,000 plus that I've heard of

1 aliens that have been interdicted and repatriated.
2 Just two days ago, it was close to three and a half
3 thousand Haitians alone.

4 There are roughly 28 countries identified
5 in the AMIO situation. We're hearing a lot about
6 Haiti and Cuba, but other countries such as China,
7 the Dominican Republic, other Caribbean countries
8 and, as I mentioned, 28 countries that are having
9 individual persons come through the maritime route,
10 let alone the land route through Mexico and Canada
11 and try to enter into the United States.

12 Last summer, it was brought to our
13 attention that the Office of Health & Safety, some
14 concerns that the operational community had with the
15 Public Health issues related to interdiction of
16 alien migrants.

17 You may recall some of the Chinese vessel
18 off of Long Beach, Long Island Jones Beach and off
19 the West Coast, the Golden Venture and some other
20 situations and these were absolutely deplorable
21 situations.

22 I wasn't there, but I saw plenty of
23 pictures and film and the human situation with
24 these, were absolutely deplorable, let alone the

1 societal situation where these folks were
2 essentially slaves, but there was real concern among
3 the operational community.

4 Twofold. One is the transmission of
5 disease to active duty personnel and, two, the
6 humanitarian concerns of the migrants themselves.

7 AMIO situations do vary, depending upon the
8 situation. The Cuban/Haitian situation is a little
9 different. They, unlike the Chinese, insofar as the
10 Chinese situation tends to be masses of people,
11 large groups, a hundred plus, sometimes as many as
12 300 people, all crammed in the hold of a vessel and
13 in the past, deplorable sanitary situations.

14 While the Caribbean situation tends to be
15 vessels of all size, many of them very small, at sea
16 for relatively short periods of time. Sometimes
17 just a matter of hours, sometimes days, very over
18 crowded, but the Chinese situation as another
19 extreme may be at sea for a year or more, crammed
20 down below holds.

21 So, obviously there is some issues. Alien
22 migrants do come from areas that are endemic with a
23 variety of communicable diseases not typically seen
24 in the U.S. Those also are diseases that are very

1 familiar, such as hepatitis and tuberculosis.

2 This started last summer with some concern
3 within our Office to try to have coherent policy
4 regarding the prevention of communicable diseases.
5 It initially started out, I had several years with
6 the CDC and so I had some colleagues there I lined
7 up with and invited the Navy to join us with that
8 because of their situation and having, as time went
9 on, increasingly involved.

10 And over a series of joint meetings that
11 took place in Atlanta and Washington, D.C., actually
12 tried to formulate policy concerning for the
13 prevention of primarily communicable diseases among
14 active duty personnel, disease transmission as well
15 as among the Haitians themselves or among the
16 migrants themselves.

17 Surveillance systems are not what we as
18 Public Health people would like to have. There are
19 no known reports that the Coast Guard have of active
20 duty personnel having had a communicable disease,
21 does not mean it doesn't exist, because our
22 surveillance systems are not -- are really
23 essentially a passive system.

24 There's regulations that says you're

1 supposed to report these things, but as far as we're
2 aware of, despite a decade plus there's no known
3 communicable diseases that have transferred,
4 particularly funds of interest such as hepatitis,
5 AIDS and tuberculosis.

6 Now, there have been instances of PPD
7 conversions and then we don't know, we don't have
8 the surveillance mechanism. We'd like to do
9 controlled studies and the like to see if the
10 conversion rates differ for those involved AMIO
11 situations, those which are not, but at this point I
12 cannot comment whether individuals have been
13 observed -- this is Coast Guard personnel -- to be
14 observed at increased transmission rate or PPD
15 conversion rates.

16 Much to our pleasure, if you will, the
17 systems aboard vessels which are primarily the
18 situation -- because it's maritime obviously -- the
19 systems, engineering systems, the operational
20 systems, the medical systems, have essentially
21 provided those control measures.

22 The prevention or to make sure that there
23 is clean and secure water and safe food practices,
24 the how do you stage migrants, alien migrants by

1 keeping them above decks, open air situations, don't
2 let them get inside of the vessel if at all
3 possible.

4 Separating food situations, appropriate use
5 of personal protected equipment and the basic
6 immunization series to date appear effective and we
7 have no reports otherwise, though they could be out
8 there, we're just not aware of it.

9 Our fear, of course, is transmission of
10 preventable disease and issues come up such as
11 should you inoculate people with the Hepatitis B?
12 What about malaria prophylaxis and on and on through
13 the list of diseases?

14 Of course, all these have costs to them and
15 expensive other resources and then Coast Guard
16 involvement is probably like other services, is that
17 people flow in and out of stuff and they're
18 stationed here and their risks are intermittent and
19 over time, so it's difficult situations.

20 I won't go into the detail of what our
21 proposals are or our current recommendations. We're
22 working very close, particular with the Navy on
23 this, to have some parallel. Our missions aren't
24 exactly the same.

1 The Coast Guard is small vessels, intercept
2 at sea. The Navy, as you are well aware, has like
3 the COMFORT, but there are certainly a number of
4 similarities and we try to have parallel operations
5 or policies which, I think, are generally so.

6 I thought I'd just leave it at the AMIO
7 situation because I thought maybe individuals might
8 be curious to that part.

9 DR. KULLER: Who is responsible for the
10 Haitian refugees now who are being sent to
11 Guantanamo and to Panama, in terms of prevention of
12 communicable diseases and preventive medicine? Is
13 it the Coast Guard or the Navy?

14 We heard a report some time ago about what
15 was an excellent program for prevention at
16 Guantanamo, but is that now still in place and how
17 is that working?

18 COMMANDER UNGS: Coast Guard involvement is
19 essentially maritime. It is the interdiction and
20 the transport, whether it's repatriation or to a
21 processing center.

22 DR. KULLER: And they get to Guantanamo or
23 they get to Panama. Who then takes on
24 responsibility?

1 COMMANDER UNGS: Yes, sir. They'd bring
2 them to -- wherever they might be, they might be to
3 Guantanamo and then the Coast Guard does not take
4 care of these individuals beyond that point.

5 GENERAL HOFFMAN: The situation in Panama
6 is unfolding and the Department of Defense's job is
7 to do what the Secretary of Defense directs that we
8 do at the discretion of the President.

9 And when the Administration decides the
10 roles and missions that the Department of Defense
11 will play and the State Department will play and
12 that other people will play, then that will play out
13 rather directly.

14 So what's going to happen in Panama, at
15 least as of yesterday afternoon, was still unfolding
16 in terms of what the policy was.

17 At Guantanamo, the operation at Guantanamo
18 is a Department of Defense operation. It is a
19 medical installation as a Navy operated
20 installation. The Air Force has put medical
21 personnel in there.

22 This was active at one time, it quieted
23 down, the numbers got very, very small, and now it's
24 being expanded again. But the basic operation of

1 Guantanamo is as it's been for the last year or two,
2 if that answers your question.

3 DR. KULLER: Well, my question would be
4 whether the Board should have any concerns right now
5 or should generate any concerns about potential
6 problems or health risks in either of these two
7 locations?

8 We heard about a year or so or two years
9 ago, I guess, about what I thought was a superb work
10 that had been done at Guantanamo in preventing
11 spread of infectious diseases and I was hoping to
12 make certain that that still is in place.

13 DR. BERG: Berg from Navy Preventive
14 Medicine Unit 2. Those were our epidemiologist who
15 were down there two years ago. At the moment, we
16 have only the hospital's preventive medicine
17 department down there. However, we are planning
18 on sending a team down to survey the situation and,
19 if necessary, we will supplement it there.

20 Part of the problem is that the Air Force
21 has some responsibility for monitoring the medical
22 care and we have to work out whether they're going
23 to do it or we are going to do it and this is a
24 matter that simply requires somebody saying yes,

1 we're going to do it so it doesn't fall through the
2 cracks.

3 But we are planning in the near future to
4 go down and assess the situation and see what needs
5 to be done to reactivate that system. I cannot
6 speak for Panama. I assume that will be an Army
7 responsibility.

8 DR. BROOME: I just wanted to mention that
9 whereas the DOD clearly has the service
10 responsibility at Guantanamo, CDC's Division of
11 Quarantine has been there in their role of looking
12 at health clearance for people actually entering the
13 country.

14 And at the same time, they've been
15 providing consultation on control issues related to
16 tuberculosis and HIV and I think it's working fairly
17 well, both with the Coast Guard on the ships for
18 refugees and also in the holding sites.

19 VOICE: CDC has been very helpful, as
20 mentioned. We had three meetings down there that
21 were joint. There were twenty plus participants.
22 The majority of them were various CDC personnel,
23 Division of Quarantine, people from the Centers of
24 Infectious Disease, NYASH, basically was trying to

1 come to some consensus and then apply that to the
2 operational arena, which is the difficulty, of
3 course.

4 And they are, at this point, -- and they
5 have done site visits for us, as an example, so
6 their assistance has been much appreciated.

7 DR. KULLER: There's another -- yes.

8 MR. HARDING: Thomas Harding. Our office
9 has been in contact with the hospital at Panama and
10 we are preparing for hospital patients that they
11 might be given.

12 DR. KULLER: Any questions?

13 CAPTAIN BERG: Berg from Preventive
14 Medicine. I have two additional comments on this,
15 one following up about the comment about the CDC.
16 Dr. Hunt Corbell of CDC called me yesterday and we
17 are starting to work out and explore the possibility
18 of whether we can monitor Haitians treated for
19 malaria, to see whether the symptom there continues
20 to be far from sensitive.

21 We also have a Preventive Medicine team on
22 board the COMFORT and the concern there is
23 tuberculosis and what is being done to prevent that,
24 so that all of the Haitians, immediately upon

1 arrival on the COMFORT, receive a chest x-ray.

2 Approximately five percent of them have an
3 abnormality compatible with tuberculosis and these
4 are kept outside of the ship, up on the weather deck
5 under canopies to prevent transmission of
6 tuberculosis to the staff on board the COMFORT and
7 to other Haitians.

8 Some of them, of course, may be HIV
9 positive. The x-rays, of course, do not tell us
10 definitively whether they have tuberculosis. That
11 evaluation will continue on at Guantanamo and
12 elsewhere, but those are the immediate steps we're
13 taking.

14 We're also concerned about measles. There
15 have been no outbreaks of measles yet. The plan is
16 to immunize all Haitians at Guantanamo with MMR
17 immediately upon arrival.

18 DR. KULLER: I would hope that you would
19 keep the Board information of what's happening with
20 the situation at both Guantanamo and Panama, in
21 terms of infectious diseases. And any help we can
22 give it there becomes a problem before it becomes a
23 big problem.

24 CAPTAIN BERG: Thank you, we appreciate

1 that offer and we certainly will keep the Board
2 informed.

3 DR. KULLER: Thank you.

4 Dr Leitch, the representative from the
5 British Liaison Office.

6 COLONEL LEITCH: Ladies and gentlemen,
7 good morning. My name is Colonel Bob Leitch and I
8 have to tell you that right now, I'm a little in
9 awe.

10 Firstly, because I've only been in my job
11 seven weeks and, secondly, because of having to
12 stand and speak in front of an audience of
13 distinguished experts and I am no expert.

14 I'm a medical staff officer, I'm not a
15 doctor and that leaves me just slightly at a
16 disadvantage, particularly in front of such experts.

17 However, my last job was working for the Surgeon
18 General, a Triservice appointment in the Ministry of
19 Defense.

20 And amongst my other tasks, I have to tell
21 you that I was intimately involved with Desert Storm
22 Syndrome for about a year, eighteen months. And as
23 the Chief Medical Planning Officer in the Gulf for
24 our own forces, I also was involved there.

1 I have a feeling, being a Catholic, that
2 one of these days I shall hit purgatory and I know
3 what purgatory is going to be and it's going to be -
4 -

5 (Laughter.)

6 COLONEL LEITCH: -- Desert Storm Syndrome
7 or something like that.

8 Before I embark on my report which will
9 have no surprises, because it's Desert Storm
10 Syndrome, the British perspective, I thought I might
11 just relate a little anecdote to you about experts,
12 because you are experts and I am not.

13 And it concerns a story of last year in the
14 center of London in summer and it was in Hyde Park.
15 And this particular lunch time there was a chap
16 feeding the ducks, minding his own business,
17 throwing bread in and all of a sudden, a football
18 whistled from nowhere, hit him on the back of the
19 head and knocked him into the water, and he was
20 knocked out and began in that shallow pond to drown.

21 Now, nobody really noticed, because they
22 don't, because people are busy. And eventually
23 somebody did and they pulled him to the water's edge
24 and he sort of lay there half in and half out of the

1 water. And then as people do, they gathered like
2 cows, you know, curiosity, they all stand and look.

3 And the crowd gathered and nobody was doing
4 anything. Eventually some busy little chap pushed
5 his way through and he said let me through, let me
6 through, I'm an expert, I'm an expert in First Aid.
7 Don't worry, I'm an expert.

8 And he then got to the front of the crowd
9 and he pulled this chap a little further out of the
10 water and he cleaned out his mouth and then he began
11 artificial respiration and he pumped away and the
12 water started to come out and he looked up and he
13 said, don't worry, don't worry, I'm an expert, he'll
14 be okay, I'm an expert.

15 And he pumped some more and more water came
16 out, and he pumped some more and more water came
17 out, and he said don't worry, I'm an expert. And
18 eventually there was a chap in a pinstriped suit who
19 said pardon me, young man, he said I don't want to
20 interrupt your accident ministrations, but I too am
21 an expert.

22 In fact, I'm a hydraulic engineer and my
23 advice is if you don't take his ass out of the
24 water, you're going to empty the lake.

1 (Laughter.)

2 COLONEL LEITCH: I somehow don't think
3 that will go in the minutes.

4 Before I get into it, I also should tell
5 you that I have tried here to avoid acronyms because
6 seven weeks into this job, I'm confused by acronyms,
7 particularly American acronyms. There was one from
8 the last presenter about alien something or other
9 operations.

10 My favorite so far -- I'm collecting them -
11 - my favorite so far came off a television program
12 recently and it was, he was a Texas Ranger and he
13 was being interviewed about illegal aliens crossing
14 the border from Mexico.

15 And he was describing -- I won't try a very
16 slow Texan drawl, because it would offend a Texan
17 and I'm sure there are some here, but this Texan
18 looked into the camera and the lady said, yes, what
19 do you do, what are you trying to you do? Well,
20 we're trying to stop Mexicans coming over the
21 border.

22 And she said yes, she said there are two
23 types of people come over the border. There are
24 Mexicans. Yeah, and who are the others? They're

1 OTMs. He said what's OTMs? Other than Mexicans.

2 (Laughter.)

3 COLONEL LEITCH: So, as you can guess, I'm
4 a little confused. Right. To our Desert Storm
5 Syndrome, the Brit perspective.

6 Why? Why are we concerned at all? Well,
7 firstly because it's a truism, when America sneezes,
8 Europe and in particular the Brits catch a cold. I
9 don't think now is the time in the morning to extend
10 that analogy to the principle symptom, which seems
11 to be diarrhea, but we are concerned.

12 And we are concerned because, as you
13 probably know, we had about 70,000 servicemen and
14 women -- if I stick to servicemen, we'll use the
15 generic, rather than the genetic term from now on --
16 so we had about 70,000 servicemen and women in the
17 Gulf of which about 50,000 are still on active
18 service.

19 We have, right up until recently, produced
20 a series of reactive measures. We've been reacting
21 to the CNN curve, that's what we've been doing.

22 And every time something happens over here,
23 we run around and around in circles back in the U.K.
24 and I do what I know a number of my compatriots and

1 peers have done here, appear in front of House of
2 Commons Defense Committee meetings and so on and so
3 forth and try to explain to people who are driven by
4 political imperatives, how difficult it is because
5 medicine, I've learned so far, is not, as much as it
6 is a science and it's a science as much as it is an
7 art and it takes an immense amount of work to
8 produce a definitive answer and I can't just do it
9 at the drop of a hat because somebody wants me to.

10 What we've done, therefore, is reached a
11 stage where we have produced what we believe is the
12 definitive statement. And our Surgeon General, a
13 Triservice officer, Sir Peter Beale, recently
14 produced what he considered to be a succinct
15 statement, which was produced verbatim in the
16 British Medical Journal last month.

17 We believe this to be the definitive
18 statement for the U.K. Armed Forces at this stage
19 and you'll bear with me if I read it to you, because
20 that way nothing will get lost in the translation.

21 And, secondly, because it is written for a
22 lay as well as an expert audience, and because I
23 know we've got at least one member of the press here
24 and that way, nobody can confuse what I say.

1 Recently, the Gulf War has been held
2 responsible for a new mystery illness, the Desert
3 Storm Syndrome or Gulf illness. I wish to describe
4 the steps being taken by the defense medical
5 services to investigate these claims.

6 During the past year, we have assessed
7 patients who have developed symptoms which they
8 maintain were caused by service in the conflict in
9 the Gulf in 1990 - '91. Because about half of the
10 troops who served in the Gulf have left the
11 services, it's not been simple to identify, let
12 alone gain access to, all those who claim to exhibit
13 these symptoms.

14 For those who are still serving, referral
15 for assessment is simple, a well established
16 procedure. For those who have left the services and
17 write directly to the Ministry of Defense for help,
18 we ask that they first see their general
19 practitioner to arrange a formal referral. The
20 assessment is then carried out. The procedure for
21 ex-service personnel has been repeatedly publicized
22 on television and radio and in the press.

23 A register of all referrals is maintained
24 at the Defense Medical Services Directorate, and was

1 under my responsibility until recently, and all
2 assessments are conducted at one service hospital
3 for clinical consistency, very much as your Tri-care
4 system is doing, we've dealt with all three services
5 in one hospital.

6 A detailed medical and occupational history
7 is taken. The particulars of the patient's
8 experience in the Gulf are determined. This
9 includes precise locations, movements between
10 locations, and the timings of those movements. In
11 addition, memorable events experienced by the
12 patients are noted.

13 A complete medical examination and routine
14 screening blood tests follow. Subjects with
15 specific, localizing symptoms and signs have the
16 relevant special investigations, which may include
17 endoscopy, biopsy, electroencephalography,
18 electromyography, computer tomography and magnetic
19 resonance imaging, et cetera.

20 We try to avoid using too rigid an
21 investigative protocol, preferring to assess each
22 patient, as required. So far, 33 Gulf veterans have
23 been referred for assessment, 33.

24 Ten had a complete assessment and have been

1 discharged from hospital follow up. We are no
2 longer interested in them; we are happy with their
3 diagnosis.

4 Eleven have had initial consultations and
5 are awaiting follow up to discuss the results of the
6 investigations. Twelve are awaiting their initial
7 hospital consultation and that was at the 25th of
8 last month.

9 The symptoms described are diverse and non
10 specific. They include fatigue, weakness, muscle or
11 joint pain, headache, hair loss, poor concentration,
12 diarrhea, depression, mood swings, disturbance of
13 sleep, breathing difficulties and cough, as we'll
14 tend to feel probably tomorrow morning. I certainly
15 will if I've got a hangover.

16 Most patients describe three or four
17 symptoms from this list, but no consistent symptoms
18 complex has emerged. The commonest symptoms are
19 fatigue and weakness. Consistent findings have
20 been an absence of physical signs and no abnormality
21 on investigation. Patients who have completed the
22 assessment have responded well to the reassurance it
23 gave them.

24 In summary, we have no evidence to support

1 the claim that a medical condition exists that is
2 peculiar to those who served in the Gulf conflict.
3 Medical statistics that we've compiled also indicate
4 that the incidence of the diverse symptoms alleged
5 to make up the syndrome has not increased.

6 There is no doubt that the symptoms
7 reported are real. What is in doubt is whether the
8 non specific symptoms of Gulf illness have a higher
9 prevalence in Gulf veterans than in the general
10 population.

11 Neither chemical nor biological weapons were
12 used by Iraq, but the threat that they posed was
13 well known to all personnel who went to the Gulf.
14 The circumstances of the conflict were therefore,
15 highly stressful and we bear this in mind in
16 continuing our investigation of Gulf illness.

17 Now, that is General Peter Beale's
18 statement, which we took about four weeks, three of
19 us, to write. Craft, argue over words and sentences
20 and get very cross with each other. That was our
21 statement and that's what we stand by and nothing so
22 far, a month on, has changed it.

23 I would mention that we have three concerns
24 at the moment, two downs and one up. Down, firstly

1 our immediate concern, and it's been already
2 articulated in this room this morning, is the danger
3 that we believe that we are in danger of creating a
4 new disease.

5 It's the effect in the short term on the
6 patients, in inverted commas, that we are seeing,
7 and whether or not we are actually doing them more
8 harm than good.

9 Number two, and probably of greatest
10 concern to us in this room, is the long term effect
11 it will have, the Persian Gulf illnesses or Desert
12 Storm Syndrome, or whatever you want to call it,
13 will have on preventive medicine in the future, on
14 our ability to deploy in the future on operations.

15 And the preventive measures that we will
16 take, particularly prophylactic measures that in the
17 past we've accepted as normal, whether or not these
18 will be limited and constrained by whatever comes
19 out of this over the next six months.

20 And last but not least, an up. And that is
21 no matter what happens, all that we go through, we
22 are certain that there was a dearth of data
23 uncollected on our part, the Brits. We did not do
24 well in collecting the sort of data that we needed

1 to argue the case and defend whatever position we
2 choose to take.

3 We know why. Firstly, because it was a
4 very short walk. Secondly, because we have the
5 lowest disease and non battle injury in our military
6 history. And last but not least, what I have termed
7 the northwest Europe Armageddon mindset.

8 And to put it in simple terms, we had spent
9 so long sitting on that 100 kilometers by 60
10 kilometers piece of northwest Europe between the
11 Elba and the Rhine or whatever, in an environment
12 where we expected a particular scenario to develop
13 that, quite frankly, who gave a damn about typhus,
14 if you're going to glow in the dark on day ten?

15 (Laughter.)

16 COLONEL LEITCH: And what happened as a
17 result in our Armed Forces, is that our preventive
18 medicine capability declined markedly. And what we
19 saw in our deployment in the Gulf War was a result
20 of this and now people like John Graham and myself
21 are scrambling around thinking good lord, did we
22 collect this, did we collect that, and we know we
23 didn't.

24 Now what will come out of this for the good

1 and has already been mentioned, we believe, is that
2 it's going to focus our minds that in the future, we
3 get back to doing it as we used to do it and do it
4 properly and collect the data, in order that we can
5 in future answer these sort of questions when they
6 come up.

7 So that really is the statement on
8 preventive medicine, the report that I have to offer
9 on behalf of the U.K. for this meeting. I'd like to
10 finish by apologizing for my compatriot, Commander
11 Clifford, not being here, the Canadian Medical
12 Forces Officer.

13 He's away doing something hugely important,
14 probably in Newfoundland or something like that and
15 I'm rather now hoping -- I notice that my Air Force
16 medical colleague, a proper doctor in the Air Force,
17 is sitting in the back doing a little quality
18 assurance, so I rather hope that I passed the first
19 step.

20 Thank you very much.

21 (Applause.)

22 DR. KULLER: Any questions? Yes.

23 DR. ASCHER: Mike Ascher. You have an
24 active Health Service.

1 COLONEL LEITCH: Yes.

2 DR. ASCHER: So access to care is not a
3 question. The comment I made earlier may have been
4 a bit cryptic, but in many cases the access to care
5 for individuals who were in the Gulf is dependent on
6 them having complaints of this type.

7 Indeed, that then becomes the basis for a
8 disability claim. As I said, this has that
9 component of a societal issue.

10 I'm wondering what you would comment on the
11 importance of that? If you did not have a National
12 Health Service, what would you have?

13 COLONEL LEITCH: Yes. This is a very
14 personal comment from a personal point of view.
15 When General Romeblank came across to the U.K., I
16 think about eighteen months ago and we sat and we
17 had a beer in Milbank and we talked about this as an
18 issue, I suggested that there were principally two
19 differences between the U.S. and the U.K. problem
20 with regard to Desert Storm Syndrome.

21 And one concerned, as we saw it, the
22 difference in age of the U.S. forces deployed. I
23 was amazed at the age of the U.S. forces because you
24 had so many Reservists deployed. We had very, very

1 small numbers and our Army is very young because,
2 you know, they only stay about three years.

3 They join when they're 18 and they're gone
4 when they're 21, so I was a particularly old man in
5 the Army. And then I joined my new job in 332
6 Medical Brigade in the 7th Corps and I was amazed, I
7 was the boy of the organization. And it seemed that
8 everybody I saw was a lot older. That was
9 number one and certainly I believe there was a
10 considerable difference in age.

11 And secondly, of course, we have the
12 National Health Service. And these individuals who
13 are Reservists, whether they are volunteers, as in
14 the National Guard or whether they have been called,
15 they go back to their own National Service Hospital
16 and therefore, they don't have the problem of
17 medical insurance and so on and so forth.

18 And, quite frankly again, a personal point
19 of view, if I had left the British Army now and I
20 suddenly had a recurring problem with, let's say, a
21 hemorrhoid, which I happen to have, and I didn't
22 have medical insurance and so on and so forth, I
23 might be a little bit pushed to say hey, I developed
24 this because I had to live on MREs for six weeks or

1 something like that.

2 (Laughter.)

3 COLONEL LEITCH: That's me putting -- and
4 I emphasize, this is a personal point of view, but I
5 have heard it expressed on a number of occasions,
6 that there does seem to be here, some sort of --
7 it's far more complex than a medical issue.

8 It's very much a societal issue and it
9 seems to be very much inter-connected. And I've
10 been watching the Senate hearings too.

11 I was there when Senator Riegle held forth
12 at Doctor Dorn recently and I got the feeling that a
13 great deal was to do with health care and the great
14 health care debate that's wracking your nation at
15 the nation.

16 And of course it worries us because we are
17 busy unstitching our National Health Service at the
18 moment, and we watch it very carefully. You sneeze,
19 we get a cold, the other way around.

20 DR. BROOME: Are you making any attempts to
21 get rates of the Syndrome or -- I mean I presume
22 these 30 that you mention as referrals are not in
23 any way a complete sample.

24 COLONEL LEITCH: They are our total so

1 far. All of them, 33, and we have tried as hard as
2 we can. We have -- we spent immense amount of
3 effort advertising it, saying look, come forward.

4 You're a general practitioner and if you've
5 got somebody who served as a Reservist and they
6 appear, then send them down to Woolwich, to the
7 Queen Elizabeth Hospital at Woolwich, and let's see
8 them because we desperately need to produce some
9 sort of answer to this.

10 We have learned a lesson. We've learned a
11 lesson over PTSD and the U.S. experience post
12 Vietnam, because we are only now beginning to feel
13 the effects from the Falklands War and PTSD over
14 the last six months.

15 And those of you who are media watchers,
16 will see we've suddenly started to have to pay out
17 money and things. So we've learned some lessons.
18 We watch very carefully what happens here because
19 this tends to lay foundations for future behavior.

20 And we're becoming as a nation anyway in
21 the U.K, more lithogenous. We're finding more and
22 more servicemen and ex-servicemen willing to stand
23 up and say hey, you owe me money here because I got
24 this as a result of.

1 You'll notice we've just paid out millions
2 for women who were discharged from the Armed Forces
3 because they were pregnant in the early and mid 80s,
4 hundreds of thousands at a time. These are lessons
5 we are very slow to learn, but when we do we pick
6 them up quite quickly.

7 And so we're being very forceful and very
8 proactive in tracing every one of these. And of
9 course, we don't have the numbers, you know, what's
10 70, 80,000 people.

11 Sir.

12 GENERAL HOFFMAN: One of the things that
13 the Department of Defense senior leadership is
14 struggling with right now, one of the form charges
15 from Dr. Joseph, the Assistant Secretary of Defense
16 for Health Affairs, is what are we going to do the
17 next time? Is there a way to do this smarter? Do
18 you need a data base of every single person who
19 goes?

20 Amazingly enough, we can't tell you who
21 went. I mean we didn't do it in such a way that --
22 we did it the normal way and the only way it just
23 sort of goes. You know, if we go to Somalia, do we
24 need to know exactly who went and how long they went

1 for and where they went, as part of the system for
2 moving them over and bringing them back?

3 Does everybody need to have mud collected
4 before they go? Does everybody need to have one
5 collected every year? I mean, do we need to collect
6 hair or what is it that we need to do to establish
7 an epidemiological -- to get the denominators in
8 these places?

9 Do we need to define a cohort of people
10 that have nothing to do with the military out in the
11 civilian world, so if we send 30,000 people
12 someplace, there's 30,000 people out in the civilian
13 world, we can go and start tracking simultaneously
14 somehow.

15 We don't know the answers to those
16 questions, but I can tell you that we are asking
17 those questions. We are asking those questions and
18 we will eventually, and eventually is a matter of
19 weeks or months, we will eventually come to terms
20 with what we plan to do so we don't end up with such
21 a terribly, terribly difficult situation in the
22 future.

23 MR. BUCKENDORF: May I make a comment? I
24 have to identify myself as the non party line member

1 of the DOD entourage here, because I believe that
2 there are a number of things that perhaps have not
3 been presented, perhaps have not been recognized.

4 And certainly I must tell you in my absence
5 from this Board for about three years, I'm surprised
6 that much of the to do that has arisen over
7 something that I think we did gather data on during
8 the Gulf War.

9 We had the Navy forward lab in place, we
10 were monitoring on a weekly basis the incidence, the
11 prevalence of diseases that were reported. And
12 quite frankly, coincidental with your findings that
13 the disease non battle injury rate was the lowest
14 ever, we plotted this against what we thought were
15 those things that the incidence rates that had been
16 prevalent in other desert warfare, basically tracing
17 it all the way back to World War One in terms of
18 what we could identify as incident rates of disease.

19 At any rate, we had that information and it
20 was amazingly low. No, we did not have the names of
21 everyone who went, but one of the things that I
22 would point out to this group, that up until about
23 two weeks ago, we had a Gulf War registry for active
24 duty military which I believe amounted to about 65

1 people. I think the number may well be higher at
2 this point in time.

3 I'm talking about the Navy, I don't care
4 about the other services because I don't represent
5 the other services.

6 (Laughter.)

7 MR. BUCKENDORF: I think you guys only had
8 one or two, so we all had very small numbers. It is
9 also amazing to note that the group that we have
10 heard most vocally from or from which we have heard
11 most vocally is a group I believe in Ashville, North
12 Carolina, a Reserve group.

13 There is a Reserve Seabee battalion,
14 construction battalion that I believe we have people
15 in Ashville, Columbus and a couple of other places.

16 The one in Ashville, I think is most cooperative.
17 The one in Columbus has been most vocal. Is that
18 correct or do I have it just opposite?

19 I'm talking to Bill Berg because Bill has
20 the most knowledge of this. We actually, and Bill,
21 in fact, has done, Bill and Steve Cunnion, have done
22 a tremendous amount to deal with these people
23 directly.

24 We have made trips with Preventive Medicine

1 teams with personnel people and a number of other
2 folks to go see these people, talk to them, record
3 their symptoms, to look at their health records and
4 a number of other things. And, quite frankly, this
5 seems to have either not been widely publicized or
6 it has fallen on deaf ears.

7 Again, commensurate with what you've had to
8 say, that group is an older group. Lots and lots of
9 rumors, lots and lots of discussions about the wide
10 number of lymphomas and other types of cancers
11 available. And when we follow up on that, it turns
12 out that that is -- it's non existent.

13 And, quite frankly, I think much of what we
14 have seen has been the inability of the Department
15 of Defense to stand up and say, there's nothing much
16 there, folks, other than a wide diversity of
17 symptoms which basically do not point to any single
18 disease entity.

19 And I believe that. I really wish that our
20 folks had the wisdom and the foresight to stand up
21 and do what the Brits have done in this regard.

22 Bill, I'll turn it over to you because you
23 have -- you may have other things to say about this,
24 but you do have all the data that the Navy has

1 gathered on these people.

2 CAPTAIN BERG: I really don't have anything
3 more to say on the data. It's been presented and
4 copies of it are circulating. I think one thing
5 that impressed me, having participated in the IH
6 Technology conference and the IOM conference of the
7 Defense Science Board is how quickly the members of
8 the Board were impressed by discussions in which
9 there was data.

10 There was not that much concern about
11 infectious diseases, because there was a tracking
12 system. Where these panel members have problems was
13 where we have limited information in the
14 environmental health issues.

15 And I think one of the lessons now is that
16 we need to have provisions in place for future
17 conflicts to collect this sort of data because I
18 think this is the best way to answer these questions
19 in the future.

20 MR. WRIGHT: I'd like to make one
21 statement. The thing that we need as the first
22 tracking mechanism are two things, one is a CATS
23 program that collects out-patient data, which we
24 have never had because we can't even tell you how

1 many active duty people have ingrown toenails.

2 We can tell you how many suture kits were
3 used, but we can't tell you what the diseases are
4 and that's been a big headache we've always had.

5 And second of all, somebody's got to
6 approach the line and tell them they have to develop
7 a real time rooster, so they know who was in Desert
8 Storm and they know who were in Somalia. And
9 without doing those two things, you will not have
10 the basis to even look at what we want.

11 GENERAL HOFFMAN: Both of those things are
12 true. I mean I think the Department recognizes both
13 of those deficiencies, ambulatory coding and --

14 MR. BUCKENDORF: I have a concern though.

15 GENERAL HOFFMAN: And the personnel
16 communities recognize that.

17 MR. BUCKENDORF: The whole CATS program
18 didn't have the diagnosis either.

19 CAPTAIN BERG: I understand.

20 DR. ASCHER: I have a concern about the
21 process from the perspective of the Board. As Chair
22 of Disease Control, I would hope we would be asking
23 questions about this in the future.

24 But I have in my hand a report from the San

1 Francisco Chronicle that concludes that the Joshua
2 Letterburg study finds no cause for illness,
3 insufficient medical evidence to support the concept
4 U.S. forces were not exposed, and a very clear
5 statement mimicking exactly what our British
6 representative said.

7 However, it is accompanied by, in bold
8 print, we firmly believe there are servicemen and
9 women who are ill as a result of this Gulf
10 experience. So this gives a mixed message at the
11 highest level.

12 We also heard the third level of mixed
13 message, which is what the screening program really
14 involves. If you go through this system, everything
15 is normal and you're still not happy, you have Gulf
16 War Syndrome. So now you have defined it just by
17 the process of looking for it and that seems rather
18 astounding.

19 DR. KULLER: I think what that doctrine is
20 submitting this afternoon -- I would say two things.
21 One, the Board did hear excellent reports about the
22 quality of preventive medicine and also surveillance
23 about the Gulf War situation at previous meetings,
24 and I think that one of the reasons that the Board

1 is very concerned here, is the fact that the quality
2 of the evaluation in the Gulf War Theater and the
3 quality of preventive medicine was superb.

4 And that in reality, the Board did make an
5 attempt, as we all know, as did many of the officers
6 who are here today, to try and confuse the situation
7 very early and it's cost, unfortunately
8 unsuccessfully as it turns out, realizing what the
9 implications.

10 Since I might have the last word before the
11 break, I can only say one other thing. It seems to
12 me that the one thing that's missing here, and I've
13 said this repeatedly, is a failure to recognize the
14 fact that psychiatric disorders are as real a
15 disease as breaking your arm or having an infection
16 or anything else.

17 We really haven't heard this. If we call
18 this Endorkin Deficiency Disease, everybody would be
19 happy, it would solve the problem and there would be
20 no discussion at all. Nobody would ask what is
21 Endorkin Deficiency Disease, what it is.

22 But I suspect in reality, that if you look
23 at people who got laid off very suddenly from IBM or
24 from American Airlines or other places, they have

1 real disease, they have very, very substantial
2 problems. But those companies in the civilian
3 sector or in populations like that, as was pointed
4 out, have developed occupational medicine approaches
5 to deal with the stresses and the fact that the
6 stresses cause a real disease.

7 They do have real diseases, it was pointed
8 out, and I think our concern is that going fishing
9 for an infectious disease agent, which is
10 extraordinarily unlikely, or a chemical exposure,
11 which is extraordinarily unlikely, instead of
12 realizing the fact that these people are sick and
13 that they do have serious health problems.

14 But that the health problems in many cases
15 may be related to the social and environmental
16 stresses that they live with, injures them more than
17 it does anybody else because essentially we don't
18 deal with the real problems. And if you don't deal
19 with the real problems, they just get worse.

20 And so I think that one of the things we're
21 hearing here and, unfortunately, most of us, I
22 guess, still have the view that having a psychiatric
23 disorder label or anything related to the central
24 nervous system, is something we don't want to have

1 or is something that's bad for you or something
2 that's really not acceptable in society, and
3 therefore, we have to find the virus or a bacteria
4 or some chemical that's causing this thing and I
5 think this may be our big problem.

6 COLONEL LEITCH: Could I make one point
7 for the Brits before I step down, sir, and that is
8 that if anybody in this room actually gets one of
9 these individuals who passes all three stages of the
10 protocol and gets out the other side, and you still
11 haven't given them a diagnosis, could we have a look
12 at them because we'd like to offer them a contract
13 from now into perpetuity for the rest of history in
14 a place in a bottle in the Royal College of
15 Physicians.

16 (Laughter.)

17 DR. KULLER: We'll take a break for about -
18 - what is it -- fifteen minutes.

19 (Whereupon, at 10:15 o'clock a.m., a recess
20 was taken until 10:43 o'clock a.m.)

21 DR. KULLER: We have now a question to
22 the Board regarding Mefloquine loading dose and
23 Colonel Schuster will make the presentation.

24 COLONEL SCHUSTER: Thank you. Malaria

1 prophylaxis continues to be an issue for the
2 military certainly, and one of the most effective
3 drugs right now, Mefloquine, is a drug which is
4 known to have a very long half life, approximately
5 21 days.

6 And so the issue comes up if somebody is
7 going to be deployed or going to an endemic area,
8 how do you get their Mefloquine levels up adequately
9 to make sure that you've maximized their protection.

10 A study was done a couple of years ago by
11 Walter Reed, the Institute of Research, in
12 conjunction with the Preventive Medicine Group and
13 the Navy Preventive Medicine Group 6 at Pearl Harbor
14 in Keneowe Bay to specifically address the issue of
15 Mefloquine tolerance and also, the issue of loading
16 dose.

17 If I can have the first slide, please. The
18 objectives of this study were to determine the type
19 and incidence of the side effects, the magnitude of
20 dizziness, which was then the prime concern for most
21 people using Mefloquine.

22 To look at safety and tolerance information
23 on a loading dose, to look at any significant shifts
24 in the sleep cycle during Mefloquine prophylaxis and

1 to define the rate of rise of Mefloquine levels with
2 the loading dose regimen versus the standard weekly
3 Mefloquine.

4 This was a double blind randomized clinical
5 trial with an active control. We did not have a
6 placebo control, because we were limited by
7 logistics in the size of the population that we
8 could handle, because this was a study that went on
9 for three months. There ended up being 359
10 participants in this study.

11 The butications were Lariam, manufactured
12 by Roche, which is what is available to our troops
13 today. It's different for our European colleagues,
14 it's a slightly different dosage than the Lariam
15 that's sold in Europe.

16 Chloroquine is also manufactured and the
17 dose used by Hoffman-LaRoche and the dosage that was
18 used was 350 milligrams. Base matching placebos
19 were made and the dosage regimens were 250
20 milligrams weekly for eleven weeks in one group.

21 250 milligram loading dose, which was given
22 on three days and then weekly for ten weeks in the
23 other Mefloquine group; and then Chloroquine was
24 given 350 milligrams base weekly in the third group.

1 This just shows the schematic for the dose
2 administration. Everybody received the same number
3 of tablets. Those in the Mefloquine weekly group
4 got a matching Chloroquine placebo with their
5 Mefloquine dose.

6 During the loading dose, Mefloquine
7 placebos were used in the groups that weren't
8 getting the Mefloquine loading dose, and Mefloquine
9 placebos were also used in those getting the
10 Chloroquine regimen.

11 One of the drawbacks of this study is it
12 was done in males, so we still don't have a lot of
13 information on females, which is getting to be more
14 of an issue now as we deploy more females into
15 endemic areas.

16 And the other thing is that these
17 candidates were all screened for use of Beta
18 blockers prior psychiatric illness, et cetera, so it
19 is -- it has to be kept in mind that this was a
20 narrow population in a sense.

21 Now, symptoms were assessed on 16 occasions
22 over thirteen weeks. There were computer scanable
23 forms, the environmental systems questionnaire, and
24 the profile of moods states. Both questionnaires

1 that are used primarily by our colleagues at NATICK,
2 who assisted us with this and they're validated in
3 the military population.

4 The third method was position interviews.
5 Now the environmental systems questionnaire consists
6 of 68 questions, which are related to the review of
7 body systems, things like I had a headache, I felt
8 sinus pressure, I felt dizzy, et cetera, and then
9 graded on intensity from zero to five.

10 The profile of mood states are 65 one word
11 evaluations of feeling, again graded on a computer
12 score sheet just by darkening a block and the
13 feelings are then grouped into six categories,
14 anger, tension, fatigue, vigor, depression and
15 confusion. And again, this is a tool that has
16 been used in the military population and is
17 validated for that population.

18 The physician interviews were non directed,
19 they were open ended questioning and our responses
20 were classified as either neurologic,
21 gastrointestinal or other.

22 The number of people in the three different
23 groups were approximately three to one in terms of
24 the weekly Mefloquine versus the loading dose

1 Mefloquine group or the weekly Chloroquine versus
2 the loading dose Mefloquine.

3 Again, this was an issue of numbers and we
4 felt we could get the statistical power that we
5 needed with this design, given the fact that we
6 didn't have access to as many subjects as we thought
7 we would have when we arrived in the field.

8 Some of the subjects received an actigraph
9 which they wore for three different periods for two
10 weeks. Pharmacokinetic samples or samples of blood
11 were taken for pharmacokinetics in the three
12 different group. Again, and all the subjects took
13 the questionnaires and were interviewed and they
14 were observed for taking their Mefloquine
15 medications.

16 Pharmacokinetic sampling in both the
17 loading dose and the weekly Mefloquine groups was
18 done just prior to dosing in weeks one, three, five,
19 seven, nine and eleven, as well as 24 hours after
20 each dose during the loading dose three days.

21 This is what the plasma levels looked like.
22 The loading dose group you can see within the first
23 three days, achieved levels that were basically
24 equivalent to the levels out at steady state after

1 eleven weeks; whereas the group that received
2 Mefloquine weekly, it took them approximately seven
3 weeks to get out into the range of 500 or so or 600
4 where the steady state pretty much exists.

5 And we used these time points to look for
6 differences as well in tolerance, between the
7 groups. In other words, during this first week, we
8 compared the Mefloquine loading dose to the
9 Mefloquine weekly dose to the Chloroquine about mid
10 point and then at the end when everybody was out at
11 steady state, we did our primary comparisons for
12 tolerance.

13 Just looking at the plasma levels, again,
14 in the 24 who were assigned to the pharmacokinetic
15 group in weekly and the 23 in the loading dose, you
16 can see at 24 hours, in other words after the first
17 dose of drug, they both had comparable plasma
18 levels.

19 But then by the third day, the group which
20 got the loading dose, clearly is out here at levels
21 which were equivalent to the steady state levels and
22 the weekly group was finally out in the same
23 ballpark.

24 And then at the end of the study, and I

1 note it to get an idea of the variability in this
2 group, we drew Mefloquine levels on everybody who
3 participated who received Mefloquine and so we have
4 here 135 subjects, here 35, and you can see again
5 this pretty much defines what the steady state
6 levels of Mefloquine would be on weekly Mefloquine
7 in this population.

8 Now, looking at the kinds of symptoms first
9 by physician interview, during the first period,
10 days 2, 3 and 4, there really weren't any major
11 differences in specific symptoms between the high
12 dose or the loading dose Mefloquine and the other
13 drugs.

14 There was a tendency here to see a little
15 more nausea, although it's not statistically
16 significant and down here, the total proportion of
17 people reporting symptoms during that first week was
18 slightly higher in the loading dose Mefloquine
19 group, but it was not statistically significant and
20 everybody -- nobody couldn't perform their functions
21 as soldiers during that period of time.

22 Looking at the overall study now, not just
23 that first week when the drug levels were the most
24 different, but overall in the study, again you see

1 now things are pretty much the same across all three
2 groups, in terms of their symptomatology, and these
3 are the kinds of percentages we see with malaria
4 prophylaxis regularly. None of these were
5 debilitating in any way.

6 Now, looking at neurologic symptoms by
7 physician review again, let's concentrate on the
8 first week when the Mefloquine levels were the most
9 different. Here insomnia seemed to be slightly more
10 frequent in the high dose Mefloquine group or the
11 loading dose group. Dreams were also a prominent
12 symptom in the loading dose Mefloquine group.

13 These were not statistically significant,
14 but overall the proportion of people reporting these
15 kinds of symptoms during that first week, was
16 statistically higher in the loading dose group.
17 Again, there was nobody here who couldn't function,
18 who felt incapacitated in their normal jobs that
19 they were doing.

20 And during this time, they were going to
21 the rifle range, they were driving their vehicles,
22 they were doing their training, et cetera.

23 Looking at the end of the study for
24 neurologic symptoms, things pretty much even out

1 across all the groups, and this is something that we
2 observed in every situation, that basically
3 tolerance occurs with time on these anti-malarial
4 medications.

5 Here there really was no major difference
6 between weekly Mefloquine, loading dose Mefloquine
7 group or the weekly Chloroquine group, except that
8 the Chloroquine group did seem to have a little bit
9 higher incidence of headaches, but otherwise there
10 weren't any major differences.

11 Looking at the neurological symptoms again
12 by physician interview overall throughout the whole
13 study, the only thing that came out that was
14 statistically significant here was dreams with the
15 loading dose Mefloquine based on that first week
16 experience. Otherwise, things were pretty much
17 comparable across the board between the different
18 drug groups.

19 Looking at dizziness and defining the 95
20 percent confidence levels, are intervals in the
21 three groups. During the loading dose week,
22 although there was a slight tendency for the loading
23 dose Mefloquine group to have higher incidence of
24 dizziness with the 95 percent confidence intervals

1 defined, there was no statistical significance here
2 and, again, nobody was incapacitated. Overall
3 throughout the whole study period, it's pretty much
4 comparable.

5 Looking at all other symptoms that either
6 weren't gastrointestinal or neurological, again,
7 basically everything comes out about the same in the
8 three drug groups. We were interested in injuries
9 primarily because if Mefloquine made you dizzy or
10 did something to your coordination, perhaps you'd
11 have an increased number of injuries.

12 Looking at the environmental symptoms
13 questionnaire just during the loading dose week,
14 here there was a slight tendency in the Mefloquine
15 groups to have more symptoms that were referable to
16 depression and again, the little higher incidence
17 here of stomachache and there was some question here
18 of coordination off.

19 None of these, these were statistically
20 significant on this test, but none of these, when
21 the physicians talked to the subjects, seemed to
22 trouble the subjects whatsoever. These were
23 questions that were answered on the questionnaire.
24 They weren't brought up in discussions with the

1 physician.

2 The profile of MOD states questionnaire,
3 looking again across the differences again, this is
4 the one that, based on 65 questions or so, defines
5 moods. There were differences, especially during
6 week five and six between the groups in the
7 intensity that was checked for these answers.

8 However, this was a period of time when
9 they were out in a two week field exercise, so there
10 were other influences in terms of the fatigue and
11 intention. But in every case here, the Mefloquine
12 group pretty much comes out a little bit ahead of
13 the Chloroquine group in intensity.

14 However, in incidence of these things,
15 there wasn't much difference and, in fact, if you
16 look at the -- if you compare these to the baseline,
17 not between groups, but to the baseline within each
18 group, none of the responses in intensity were
19 outside of the expected baseline responses in this
20 group of patients.

21 So nothing here, if you looked at the
22 individual questionnaires, would have been
23 considered outside the norm for this group.

24 Now, in an attempt to get some kind of a

1 handle on sleep, we used the actigraph which was a
2 wristwatch size computerized activity monitor, which
3 our neuropsychology, neuropsychiatry folks at Walter
4 Reed use for a number of studies and have pretty
5 much validated this for measuring the impact of
6 sleep in a number of studies.

7 It basically is a motion recorder and is
8 scored by a computer and we were interested in three
9 basic times that we monitor. Unfortunately, about
10 48 percent of these actigraphs went on the blink at
11 sometime or another during this and so, we had to
12 pool the data.

13 But when we pooled the data, nothing here
14 is going to be statistically significant because of
15 that, but we saw some trends. In the Mefloquine
16 groups, there was a slight decrease of about 20
17 minutes in the total sleep time per night compared
18 to the weekly Chloroquine group.

19 The percent sleep here is just slightly
20 less. This is clearly not statistically significant
21 here. The average activity, that is how restless is
22 your sleep, Mefloquine sleep seemed to be a tad more
23 restless, but again nothing that we could say was
24 significant in any way.

1 The global index basically tells you about
2 the quality of sleep and is a measure of
3 restlessness and periods of sound sleep. The higher
4 the score, the worse the quality of sleep.

5 This is -- again the Mefloquine groups were
6 slightly higher, especially the loading dose group
7 here, but nothing that could possibly be said to be
8 significant, although if you take it in light of the
9 questionnaire responses and so on, there may be
10 something to Mefloquine and sleep, which I'll get
11 into in a minute.

12 We looked also at all the people on the
13 study who might have reported to sick call during
14 this three month period and pretty much all the
15 kinds of complaints at sick call were pretty much
16 even across the board. There was no preponderance
17 of injuries in Mefloquine versus the other, none of
18 that was significant.

19 So the most frequent neuro-psychological
20 side effects that were seen in this study, with all
21 three regimens, were insomnia, headache, vivid
22 dreams, dizziness and irritability. The physician
23 interviews, neither Mefloquine regimen produced more
24 dizziness than Chloroquine.

1 On the ESQ, the dizziness during the
2 initial week of the study was reported in a
3 significantly greater proportion of the loading dose
4 Mefloquine group, but no functional impairment or
5 sick call visits were attributed to dizziness.

6 The upper limits of 95 percent confidence
7 intervals for dizziness were 10 to 17 percent for
8 the three drug groups. The loading dose Mefloquine
9 produced some alteration in the duration and quality
10 of sleep. Feeling depressed was reported on the
11 palms and ESQ more frequently in the Mefloquine
12 recipients.

13 Following the three day loading dose
14 Mefloquine levels were equivalent to the steady
15 state levels, measured after eleven weekly doses of
16 Mefloquine and decreasing reports of symptoms
17 occurred over the course of the study, suggesting
18 tolerance to the drug side effects.

19 Some other data that I've received from
20 Hans Lobell at the CDC, in his conversations with
21 the Dutch Army, there are three contingents here of
22 Dutch Marines who were sent over to Cambodia. Each
23 one was over for about six months, starting in late
24 1992. This was the first half of '93 and the second

1 half of '93.

2 The first contingent got over in a
3 situation where their quotas and so on, weren't
4 quite ready and had some problems with some
5 infectious diseases here, but basically this
6 contingent and this contingent were both on weekly
7 Mefloquine.

8 This contingent was given a loading dose of
9 Mefloquine, and you can see -- and they were given a
10 questionnaire 48 hours after -- I'm sorry, four
11 weeks after they had been in the field.

12 So this is four weeks after they got either
13 their loading dose or began weekly Mefloquine and
14 you can see there's, you know, in terms of the
15 symptoms that are reported, there's really no
16 difference between these contingencies. I don't
17 have data on efficacy, but it wouldn't be comparable
18 any way because they were at different times.

19 Hans Lobell also gave me this which, those
20 of you who come to the malaria meetings, the Federal
21 Agency malaria group meeting, have seen before.
22 This is data from the Peace Corps when they were on
23 a bi-weekly Mefloquine regimen and the purpose
24 of this was to look at when the failures occurred

1 and basically they occurred mostly during the second
2 week of the bi-weekly therapy with Mefloquine
3 or prophylaxis, when the levels tended to be below
4 these levels, these blood levels.

5 This was used to model a concentration
6 efficacy or a prophylactic efficacy model that the
7 CDC used. And basically, using this probit
8 regression, they're estimated efficacy at these
9 blood levels of Mefloquine, to get, you know, up in
10 the 95, 90 percent, you're talking about having
11 blood levels six, 700 and blood levels tend to be
12 slightly higher than plasma levels, so plasma levels
13 would be lower than these, slightly lower than these
14 blood levels.

15 So their prophylactic efficacy, based on
16 that kind of a model for 90 percent in that area of
17 Africa, would be about 460 or so. And if you look
18 at the blood levels in our study, the plasma levels
19 in our study, you can see that 650 or so is the mean
20 steady state levels, which would certainly be
21 adequate to give optimal protection in troops in an
22 area where the parasites are Mefloquine sensitive.

23 And you can see, again, if you look at the
24 different time points in the group that was just

1 dosed weekly without the load, how long that they
2 were basically below these optimum levels.

3 So it would appear -- we can have the
4 lights on. There's certainly evidence
5 pharmacokinetically to validate a loading dose
6 regimen of Mefloquine to show that you can easily
7 achieve the steady state levels within three days.

8 It would appear again, from the very
9 limited study that we did in Hawaii, that this
10 loading dose is pretty well tolerate. That, along
11 with the data from the Dutch Army, again, would
12 support that that loading dose is pretty well
13 tolerated.

14 There are no efficacy studies on whether a
15 loading dose is really better than a non loading
16 dose, although certainly, theoretically, you can see
17 that it would make sense. There is no tolerance
18 data on females at this point and, certainly, their
19 smaller body weight might play a role in their
20 tolerance of a lading dose.

21 Are there any questions?

22 MR. CHIN: Jim Chin. Is there any concern
23 abut Mefloquine reactions in individuals with G-6 PD
24 positions?

1 COLONEL SCHUSTER: No, no.

2 COMMANDER UNGS: Tim Unga. I know your
3 study did address it, but as quoting the numbers as
4 a research concern for the effects of the problem
5 issues and decision making. I wonder if you could
6 make comments about, as a program policy, that
7 tetracycline, a form of tetracycline may be a first
8 choice with all the concerns people have with the
9 side effects.

10 COLONEL SCHUSTER: Tetracycline has its own
11 set of side effects which, in many cases, are worse
12 than Mefloquine's in terms of GI. The Mefloquine --
13 these symptoms again, measured on these scales, from
14 a practical standpoint didn't interfere with any of
15 these guys' tasks that they were doing, and they
16 were basically Marines in barracks in training, as
17 well as during two weeks out in a field operation
18 environment.

19 There's always going to be, you know, and
20 they say it's one to 13,000, one to 10,000 incidence
21 of neuro-psychiatric reactions that may be
22 significant. Clearly, our population is too small
23 here to measure that, but I think, you know, it's a
24 risk benefit kind of thing and I think we're running

1 out of drugs to use.

2 I think the overall impact of Mefloquine
3 is, at those doses, is pretty innocuous, but there's
4 a good chance there will be an individual here and
5 there that's going to have an undue effect.

6 There's been, you know, if you look at
7 Stephan's Travelers questionnaires that the Swiss
8 studies, there are tens of thousands of people that
9 have been monitored on the various animal aerial of
10 prophylactic regimens. Weekly Mefloquine has a very
11 low incidence, certainly no different than
12 Chloroquine endoxy, in terms of its side effects.

13 COMMANDER UNGS: Just a couple of pieces
14 that you noted are not here to help us make what I
15 think is a key decision and strictly key, given the
16 Air Force's ongoing concern about seeing the side
17 effects of Mefloquine, et cetera.

18 The first of which is it depends how you
19 look at that data. I mean, as you said before, in
20 any of those numbers between weekly and high dose
21 Mefloquine, the loading dose, are not statistically
22 significant, but in most categories, particularly
23 early on, it was double the rate, two to four, three
24 to six, seven to nine.

1 And what concerns me is in that weekly
2 study, you only had 46 individuals in the loading
3 dose numbers. And while it's important information,
4 it seems to me that --

5 COLONEL SCHUSTER: We were expecting --
6 yeah -- we were -- again, it is and it was intended
7 to point us in a direction for further study, but we
8 were expecting to see larger differences produced by
9 the drug, the loading dose versus the weekly. And
10 so that's why the sample size was smaller.

11 COMMANDER UNGS: I understand that. I'm
12 not criticizing, I'm just saying that as I sit here
13 kind of looking at through my prism, the other issue
14 when you get to the bottom in your summary total,
15 that the one statistically significant finding you
16 did have, is that 38 percent versus 19 percent of
17 those in the loading dose did have side effects.

18 COLONEL SCHUSTER: Right. The proportion
19 of people complaining of those side effects was
20 greater. For any individual side effect, there was
21 no statistical difference.

22 COMMANDER UNGS: Right, I understand.

23 COLONEL SCHUSTER: And again, the physician
24 interviews thrown into that questionnaire would seem

1 to confirm that none of these were of particular
2 concern to the subjects.

3 In other words they weren't -- yeah, they
4 were checking them off on the sheet, but when
5 interviewing the physician and talking about how do
6 we go and so on, there weren't anybody who -- there
7 wasn't anybody who really had a complaint specific
8 to that in any particular group.

9 And when you looked at sick call and
10 everything else you could monitor, there didn't seem
11 to be anybody who was running into a problem
12 performing their job or anything like that. But
13 clearly, it's in small numbers. There's no doubt
14 about it.

15 COMMANDER UNGS: The other piece of it is
16 the advocacy piece. I mean, looking at the Peace
17 Corps data, which is kind of retrospective, looking
18 at failures and assuming that we did a full
19 compliance, the question that I've got is if it
20 isn't effective for up to eleven weeks of using it,
21 and we've been using it in DOD since --

22 COLONEL SCHUSTER: I don't think it's
23 ineffective for eleven weeks. I mean, you know,
24 it's a relative thing and it depends on what

1 parasite you happen to get hit with and so on.

2 COMMANDER UNGS: Right.

3 COLONEL SCHUSTER: I think in Southeast --

4 COMMANDER UNGS: I guess psychologically
5 we've been using it for ongoing two years and I'm
6 not aware, within the military, of appreciable
7 failures or even we haven't been seeing population
8 based data that looks at efficacy of a loading dose
9 in a field setting versus another dose of that study
10 that's been done.

11 And I guess what I'm saying is I see the
12 question being a little premature, both in terms of
13 the side effect data and in terms of clinical
14 efficacy data, particularly given that when
15 Mefloquine first came out, we had a loading dose.

16 We had not simply a loading dose, but we
17 had details and basically CDC backed off on and if
18 it has been that effective, I guess from a policy
19 issue, that I guess this would be malaria group too
20 and I want to raise it to this Board.

21 If it is shown to be sub-therapeutic,
22 either in vivo or in vitro, why aren't we seeing
23 more movement from CDC along these lines?

24 COLONEL SCHUSTER: You know, I think again

1 it depends on where the soldiers are being deployed.

2 I think that's -- one of the issue is that there
3 are parasites in certain parts of the world that are
4 becoming more and more resistant to Mefloquine and
5 so there you don't have as much of a breather in
6 terms of the blood level that you generate.

7 They're pretty sensitive and so even after
8 a couple of doses of Mefloquine, you're going to be
9 able to keep things under control, whereas if you go
10 into Southeast Asia you could probably take a
11 loading dose in some parts of Thailand on the
12 Cambodian border, and it still wouldn't make any
13 difference, you're going to get, you know, malaria.

14 But the idea was or the concern was, I
15 think, that you at least optimized the level in an
16 area that you went into where there was the
17 possibility that the parasites might be less
18 sensitive.

19 The other thing was that some of my
20 colleagues have told me there was some question in
21 Somalia with some switching of drugs, between
22 Doxycycline and Mefloquine, and whether or not
23 people were put into situations where they were at
24 risk before the Mefloquine levels had a chance to be

1 adequate.

2 And so in that kind of a situation or where
3 somebody had to mobilize in a hurry, is there an
4 alternative?

5 This is not meant to be something, you
6 know, if you know you're going to be deployed six
7 weeks from now or three weeks from now in an area
8 where, you know, where malaria isn't much of a
9 problem or it's a low risk, I don't think there's
10 any point to loading.

11 I think if you had to move a group out
12 within a week to an area where there was some
13 insensitivity to Mefloquine or a potential to that,
14 that might be a different issue.

15 COMMANDER MITCHELL: Commander Mitchell,
16 Naval Health Center. Just a follow up comment to
17 Air Force concerns. We certainly are interested in
18 the Mefloquine loading dose. I believe the military
19 experience of the last two years. The only intense
20 exposure we've had to malaria would probably be
21 Somalia in that experience.

22 We have some suggestions that there are
23 some individuals who could have benefitted by
24 perhaps a loading dose, particularly individuals who

1 have to shift from Tetracycline or Doxycycline ro
2 Mefloquine .

3 The Naval forces have a particular concern
4 because they're subject to very short deployments,
5 particularly if you're floating and you do not have
6 the opportunity, as many of the perhaps large Army
7 units, to take a more unhurried approach and take
8 perhaps a month. Some of the special forces in the
9 Army share our concerns.

10 When I talked to Hans Lobell at CDC, CDC's
11 recommendations were geared to a different
12 population, not specifically a military audience.
13 They will admit the average American tourist
14 travellers.

15 They do not have a heavy exposure in their
16 typical tourist destinations. Perhaps out of
17 medical prudence, they certainly are recommended to
18 take a hema prophylaxis, but their real exposure is
19 pretty minimal.

20 Putting troops in under combat situations,
21 the insertion of troops where you have minimal
22 opportunities for personal protective measures, in a
23 broader sense is a different threat environment and
24 most of the experts at the inter-agency malaria

1 group recognizes the military is a unique population
2 and certainly should have a thorough consideration
3 of the Mefloquine loading dose because the CDC does
4 have a different population and we certainly
5 acknowledge that.

6 DR. KULLER: Can we summarize? It
7 seems to me that what we've heard is that there is
8 an implied need, but we're not sure how big that
9 need is for a loading dose.

10 There are certainly side effects associated
11 with Mefloquine in the loading dose and the issue is
12 basically what the risk benefits might be,
13 especially in certain high risks groups and whether
14 there should be any further research, it seems to
15 me, to determine whether we would consider using a
16 Mefloquine loading dose.

17 That's basically the way I can understand
18 it, but there's no data that says there actually is
19 a risk right now in Somalia or anywhere else, that
20 says that we've actually shown that because we
21 didn't have a loading dose, we actually had a
22 malaria problem, or is that -- or is it just -- what
23 I'm getting it's more hearsay than actual data.

24 COLONEL SCHUSTER: That's an answer for the

1 Preventive Medicine people.

2 COMMANDER GRAY: I think that data will be
3 published in the next few months. Mark Ross out at
4 the Naval Hospital in San Diego is publishing that
5 data. But we had experience in two locations in
6 Somalia where we had the opportunity to observe
7 malaria, and switching regimens in the fact of
8 exposure to malaria and did see that the Marines who
9 did develop malaria after being switched to
10 Mefloquine, developed malaria in the first several
11 weeks of being switched over and that seemed to be a
12 problem.

13 The second location was where we had an
14 opportunity of having troops that were co-located,
15 some troops on Doxycycline and others on Mefloquine.
16 And in that situation, the only case of malaria
17 that occurred in a soldier that was on Mefloquine,
18 occurred in the first week after arrival in the
19 country. That's the only data that exists.

20 DR. KULLER: And I ask Dr. Ascher, as head
21 of the Infectious Disease sub-group, who is already
22 hard at work at it, to prepare the response and
23 we'll have that back tomorrow morning.

24 Thank you very much. Dr. Broome, do you

1 want to comment?

2 DR. BROOME: I thought the experience in
3 Somalia was extremely relevant. I wonder if you
4 could just tell us approximately how many cases of
5 malaria were seen in those first weeks?

6 COMMANDER GRAY: How many cases total in
7 the first week after switching? No, I don't know
8 that. There were 48 cases in U.S. troops in country
9 total. Of that number, how many occurred in the
10 first week after switching, I don't know.

11 DR. BROOME: You just said that it
12 appeared to be a tendency for the cases to appear
13 within the first weeks of switching regimens to
14 Mefloquine and I just didn't have a sense of whether
15 you were talking about two cases or 40 cases within
16 that initial period before you would have expected
17 to reach the plateau.

18 COMMANDER GRAY: Of that total of 48 cases
19 that occurred in country, roughly half, about 24
20 occurred in one location, Bardera, which is where
21 the Marine unit went in on Doxycycline and then were
22 switched to Mefloquine.

23 How many of the Marines developed malaria
24 while they were still taking Doxycycline versus

1 Mefloquine, I don't know. I don't really have --
2 I'm not writing this paper. I hear about it, but I
3 don't have the data.

4 CAPTAIN BERG: Berg, Navy. I'm trying to
5 remember the figures off the top of my head, but I
6 think it was something like those who were on
7 Mefloquine had a rate of one case of malaria per
8 10,000 per week.

9 Those on Doxycycline had a rate of about
10 five and those who switched from Doxycycline to
11 Mefloquine, had a rate of about 25. I don't recall
12 the time when they got it, but clearly the big
13 problem was with the switch.

14 DR. KULLER: Is there any problem with
15 Mefloquine in terms of performance? Do we have any
16 data on performance of troops when they're on
17 Mefloquine?

18 COLONEL SCHUSTER: There are no performance
19 studies per se, other than the observations here and
20 right now, Swiss air pilots are being studied by the
21 CDC to look at their performance because aviation
22 has always been off limits to Mefloquine.

23 DR. KULLER: Do the passengers on the
24 plane, when they take off, know that these people

1 are in a clinical trial?

2 (Laughter.)

3 DR. KULLER: Any more questions about this
4 particular subject? Dr. Ascher, Mike, do you have
5 any questions? Okay, we'll have a report back to
6 you tomorrow morning.

7 Okay, we're going to move now to the next
8 topic. Dr. Helmkamp is going to talk about suicide
9 among active-duty military males.

10 DR. HELMKAMP: Not to belittle the Gulf War
11 Syndrome problem that we're all talking about, but
12 recently I presented this data to a group of
13 officials in Washington and afterwards, I was
14 talking with several of my colleagues, including
15 Steve Kenyon and Bill Yang at BuMed, and they asked
16 me several questions.

17 Have you had thinning and losing gray hair?

18 Have you lost weight? Are you fatigued? Are you
19 nauseous? Have you had diarrhea? I said yes to all
20 of those and the reason why is several days before
21 this brief, and actually several minutes before the
22 brief and during the brief, which happened to be to
23 the Surgeon General, I had all of those.

24 So I qualify as a person who has the

1 syndrome, but I wasn't anywhere close to it. So
2 we're going to come across these type of people, but
3 some of the criteria are so general that we all
4 qualify for it. And I think certainly with the
5 stress in parts of our jobs, it's been alluded to
6 before, it's going to be very hard to work all this
7 out.

8 I appreciate the opportunity to present
9 this suicide data to the AFEB today. This also
10 reminds me too of several years ago when Dr. Kuller
11 was on the other side of the table, just like we are
12 right now, as I was defending my dissertation, he
13 was the Department Chair at Pitt and I feel a little
14 bit more confident today than I did eleven years
15 ago.

16 Copies of these overheads are provided and
17 included among these slides are several summary
18 tables, which were taken from a manuscript that is
19 currently in review at Military Medicine. Also,
20 there's a companion paper on homicides of the
21 military for the same period of time.

22 And that raises a pet peeve which I want to
23 mention, and I won't mention it again, but for us
24 military active duty people who want to get out

1 military specific data, we use Military Medicine as
2 a main means to do that, and if it takes four months
3 just to acknowledge receipt of a manuscript, that's
4 unsatisfactory.

5 And then Lord knows how long for the review
6 process, to know whether or not it's accepted or
7 not. And us in the military who want to publish in
8 a military journal, that's very, very frustrating.
9 So if the AFEB of the Offices of the Surgeon
10 Generals can help, I and I think many others would
11 be very appreciative.

12 Also included in your handouts is an
13 article which I recently published in JOM on the
14 fatalities in the Persian Gulf compared with the
15 other services.

16 Next slide, please.

17 For my presentation this morning, I will
18 provide a thirteen year summary of suicide among
19 active duty males and compare rates and trend
20 information with military female suicides and also
21 national data. I will also provide a typical
22 service specific demographic profile of a suicide
23 victim.

24 Further, I will present high risk

1 occupational groups, both in terms of suicide
2 distribution and rate of occurrence for each of the
3 four services.

4 Finally, if time permits, I will provide
5 some trend information in relation to the DOD
6 Healthy People 2000 objective related to suicide
7 among males aged 20 to 34.

8 Two years ago, I presented development of a
9 DD-1300 based data base to the AFEB. Since then,
10 the data covers thirteen years, 1980 to 1992, and
11 contains information on over 25,000 deaths, from a
12 population of over 27 million active duty military.

13 Since 1990, information on the
14 circumstances of death in the military and the
15 method of death are no longer available on the DD-
16 1300s. This severely limits comparisons to NCHS
17 data, death certificate data.

18 The DD-1300 is the main source of input of
19 data for the worldwide casualty system run by DOD.
20 For the two populations that we'll compare this
21 morning, the age ranges are similar, the E codes are
22 similar and the rates are all expressed per 100,000.

23 Civilian death information is based on NCHS
24 statistics from death certificates.

1 Next slide, please.

2 Looking at distribution of fatalities among
3 males in both populations, you'll see that suicide
4 is the second leading cause of non disease death in
5 military males.

6 Next slide, please.

7 Among females, the distribution is exactly
8 the same as with males. However, this is the third
9 leading cause of none disease death in women, second
10 to accidents and homicide.

11 Next.

12 Looking at overall rates by service, you
13 observe that the Marine Corps has the fewest number
14 of suicide victims, but they have the highest rate
15 of 13.65. That is accrued rate.

16 The almost 3,200 suicides in the thirteen
17 year period is some two and a half times more deaths
18 from suicide compared to homicides.

19 Next.

20 Looking at gender specific rates in both
21 population, rates among civilian males are nearly
22 double that of military males, 24 versus about 13.
23 Rates among civilian females are only slightly
24 higher than their military counterparts. And male

1 rates are substantially higher in both populations,
2 compared to their female counterparts.

3 Looking at gender specific rates within
4 each of the services, both male and females have the
5 highest rates in the Marines, although the female
6 rate is based on only nine cases.

7 Civilians have higher rates in all age
8 groups, although only slightly so in the youngest
9 group, 17 to 19 year olds.

10 Looking at service specific rates again for
11 the four age groups, Marines had the highest rates
12 through age 34 and only a slightly lower rate in the
13 oldest age group, 35 to 54.

14 The racial patterns of suicide rates were
15 similar in both civilian and military populations.
16 And race in service rates, the Marines had the
17 highest rates among both whites and blacks and only
18 slightly lower rates than the Army among personnel
19 by the races.

20 On this summary table there are a couple of
21 key points to be made. Males generally are an
22 elevated risk in all age groups in both populations.
23 White males in particular are at the highest risk.
24 While the rates among military males are high, they

1 are still lower than the same sub-groups in the U.S.
2 population.

3 Now, more specifically looking at women,
4 which I think you might find interesting, Air Force
5 females in the 20 to 34 year age group, both black
6 and white, have rates at 6.6 and 5.5 per 100,000,
7 which are greater than civilian rates.

8 And then looking at white females in the
9 two older age groups among Army women, 37 cases with
10 a rate of 8.8 in women 20 to 34 in the Army and then
11 those age 35 to 54 have a rate of 19.45 only based
12 on eleven cases, but these rates are also higher
13 than national rates.

14 Next.

15 Looking at officer enlisted status or
16 surrogate for seniority, we see that enlisted rates
17 of suicide are generally nearly double the rates
18 among officers. Rates in the Navy enlisted
19 community, steadily decrease as pay rate increases.

20 However, this does not hold for the other services,
21 where the rates vary through enlisted status.

22 This table, the previous one and the
23 following one, are those tables that are in the
24 Military Medicine manuscript. And then the next

1 table is a summary of what I've just discussed and I
2 won't go into it, but it is a summary table for your
3 review later.

4 Looking at trends now, comparing U.S.
5 males, their military counterparts, and females and
6 their counterparts in both populations, you notice
7 that the rates are very steady for both males and
8 females in the U.S. population.

9 Military rates, particularly among females,
10 show a lot of tempo variability because of the few
11 number of cases; in particular, among military
12 females. In the years '80, '84, '87, '89 and '91,
13 there were fewer than ten cases, which would
14 obviously cause this tremendous change in rates.

15 This is a chart I obtained from the Bureau
16 of Naval Personnel last week and it has fiscal year
17 1993 data for the four services and generally the
18 rates for Army, Air Force and Navy are about the
19 same or a little bit higher than last year.

20 However, the rate in the Marine Corps is a
21 precipitous increase over what it was in previous
22 years. Again, this is fiscal year information.

23 Next slide, please.

24 Adding the information we just saw, but

1 modifying a little bit for the Navy and Marine Corps
2 to shift to a calendar year basis, and leaving the
3 Army and Air Force at fiscal year basis, again we
4 see the later three services have a slight increase
5 from '92 to '93, and the Marine Corps ends up with a
6 rate in 1993 of 21.1, which is the highest rate in
7 fifteen years, based on the highest number of
8 confirmed cases, 37 since I -- of the data that I
9 have.

10 Eight of these cases were at AFOSI in Camp
11 Pendleton early last year.

12 Next, please.

13 Now looking at just males, which is the
14 focus group of these presentation, again we see the
15 U.S. male rates are very steady and all four
16 services have rates that are well below the U.S.
17 rate. However, they exhibit much greater temporal
18 variability and that variability is very much the
19 same as what you saw previously because of the very
20 few female cases.

21 Next, please.

22 Summarizing a demographic profile of the
23 military suicide victim, we can make several
24 observations. This is very much a male, white

1 phenomenon, where overall in the military about 95
2 percent of the suicide victims are male and about 83
3 percent are white.

4 In terms of pay grade, for the Air Force,
5 Army and Navy, they are essentially second termers
6 where they're E4 to E6, average age around 25 to 26.

7 In the Marine Corps, they're much younger at about
8 age 24-1/2 and it's the same between males and
9 females and they're first termers. Half of military
10 suicides, Marine suicides are E1 to E3.

11 In the Air Force, there are about an
12 average of 64 suicides per calendar year. In the
13 Army, there are about 93. Marine Corps about 27
14 through 1992. It will be higher on the average,
15 about 30 now through '93, and in the Navy about 62
16 per year.

17 Next.

18 Now shifting a little bit on to the manners
19 in which military individuals kill themselves or
20 commit suicide. Comparing civilian and military, we
21 see that it looks like the military is just a sub-
22 set of the U.S. distribution here.

23 In terms of the type of means they use to
24 kill themselves, the percentages are very much the

1 same, very little difference.

2 Among males in each of the services --
3 switch, please -- we see that Marines use firearms
4 in about three-quarters of all suicides among the
5 290 cases. A smaller proportion in each of the
6 other four services use firearms.

7 In the Navy, I'll point out that 18 percent
8 of the suicide victims hung themselves, which is the
9 second bar up and 22 percent used drugs or motor
10 vehicles to commit suicide.

11 Next, please.

12 Looking at females, we see there's quite a
13 difference. I don't know if it's statistically
14 significant or not, but 55 percent of military women
15 use firearms.

16 One might pose the question, is this
17 difference explained by the military females'
18 familiarity with firearms? I don't have an answer
19 to that, but the question is posed.

20 Looking at females within each of the
21 services, within the Air Force about two-thirds of
22 the female suicide victims use firearms and lower
23 percentages in the other three services.

24 In the Marine Corps, 22 percent of the

1 women, again only based on nine cases, use carbon
2 monoxide as a means to kill themselves. And within
3 Navy women, a third use drugs and a third hung
4 themselves.

5 Next, please.

6 Looking at racial differences on the method
7 of suicide, there are no notable differences
8 observed between whites in both populations.
9 Looking among the military whites specifically,
10 there are no notable differences here.

11 The most obvious observation is again,
12 about three-quarters of Marine Corps whites used
13 firearms. The method used by blacks and persons of
14 other races is similar in both populations also.

15 Next, please.

16 The next five charts deal with the
17 occupational distribution of suicides among males
18 and then a sub-group of males 20 to 34, which is the
19 focus group on the DOD Healthy People 2000 Suicide
20 Objective.

21 In Air Force males, we see that among
22 security and law enforcement specialists, about nine
23 percent of all male suicides occurred in that group
24 and a little higher percentage occurred in the males

1 aged 20 to 34.

2 Also, they resulted in what I'm calling an
3 occupational risk ratio -- I'm sorry, a rate of
4 about 16.3, which is significantly higher than the
5 12.1 per 100,000 among all Air Force males aged 20
6 to 34. This rate comparison results in what I'm
7 calling an occupational risk ratio of about 1.4,
8 which is statistically significant as shown.

9 Looking at two other occupational groups
10 within the Air Force, airman, patients and officer
11 trainees, which is kind of a potpourri of groups,
12 but nonetheless they were coded on their 1300 as 990
13 blank blank, had a significant rate at 46.5 per
14 100,000 in the high risk group of males 20 to 34.

15 And the third group I'd like to point out
16 is medical and surgical service specialists,
17 resulting in a rate of 20.6 and an occupational risk
18 ratio of about 1.7. I might point out too that the
19 544 suicides among males aged 20 to 34 is about 70
20 percent of all suicides in all males of the 733
21 suicides.

22 Turning now to the next chart in male
23 occupational groups which are at high risk, we see
24 infantrymen, occupational code of 11B, comprised

1 about 12 percent of male suicides and about 12-1/2
2 percent of those in the males aged 20 to 34.

3 This resulted in a rate of about 21.2 per
4 100,000 and an occupational risk ratio of about 1.7,
5 which was significant P=0.000. And then also, in a
6 similar fashion to the Air Force, military police in
7 the Army are at high risk, resulting in a rate of
8 18.6 in males 20 to 34 and a risk ratio of 1.41,
9 significant at .05

10 This sub-group of males, 20 to 34,
11 constitutes 73 or nearly three-quarters of all male
12 suicides, the 839 divided by 1144.

13 Turning to the Marine Corps now, we see
14 that riflemen, 0311 MOS, comprise 13 percent of the
15 male suicides and about 12 percent of those in the
16 male group of 20 to 34. Although all rates, but
17 those in mortarmen, exceeded the 14.18, none of the
18 rates were significant, based primarily on low
19 numbers of cases.

20 In the suicides among the middle age group,
21 20 to 34, was exactly three-quarters of the 336 male
22 suicides. And looking, finally, at Navy males,
23 which is on this table and the following table, we
24 have two groups that are particularly high risk.

1 Although the machinist's mates had the
2 highest number of suicides in both all males and the
3 male specific group at 20 to 34, they don't have a
4 significant occupational risk ratio. However,
5 seaman recruits and seaman apprentice do.

6 Among seaman recruits, the 20 cases
7 resulted in a rate of 27.32 and an occupational risk
8 ration of 2.2, significant at point zero zero zero.

9 And then among seaman apprentice, the 19 cases over
10 the thirteen years, resulted in a rate of 20.9 and
11 an occupational risk ration of about 1.7, compared
12 with the overall rate of 12.6 or so in all Navy
13 males in that age group.

14 And again, about three-quarters of the male
15 suicides were out of the male group of 20 to 34.

16 Now, the final portion of my presentation,
17 I'm going to shift gears a little bit and
18 specifically talk about a Healthy People 2000 goal
19 that was developed by the Public Health Service some
20 years ago and amongst their hundreds that they
21 developed, and one that the military adapted
22 verbatim, rights and all for each of the -- well,
23 collectively for the military and I presume for each
24 of the services.

1 However, I find specifically some problems
2 in adapting verbatim, if you will, some of the
3 Healthy People 2000 objectives to a military
4 population. First of all, national data bases such
5 as NCHS or NIOSH, do not reflect military
6 demographics.

7 We are a group that is 90 percent male, 75
8 percent white and 98 percent of us, myself excluded,
9 are 45 or younger. Less than three percent of
10 military deaths are captured in national data bases.

11 Some objectives and goals are not service
12 specific. The ones that we have adapted in DOD are
13 not service specific, and the monitoring of military
14 progress towards national goals is very problematic
15 and difficult, at best.

16 Next.

17 The specific goal I am discussing from the
18 national levels is 7.2 Bravo, which is violent and
19 abusive behavior, whose goal is to reduce suicides
20 to no more than 21.4 per 100,000 among males aged 20
21 to 34. This is based on 1987 NCHS data.

22 Now, the military goal, which I would
23 propose and this is based on the DD-1300 data base
24 that I've developed over the last couple of years

1 called MILTOF, should read -- will be the number 21
2 clinical and I'm paraphrasing what it actually is.

3 Reduce suicides in the military to no more
4 than 11.4 per 100,000 among males aged 20 to 34.

5 Looking specifically at each of the
6 specific services, and again, based on 1987 data,
7 one may choose another year where rates might be
8 lower; therefore, if your rates are lower, your
9 reduction is changed. But I chose to use 1987 to
10 match exactly what the national population was
11 using.

12 So based on the 1987 number of suicides and
13 the base rate for that year for each of the
14 services, one can develop a goal rate for the year
15 2000 and this goal rate, again being consistent with
16 1987 national goals for the year 2000, represents a
17 fifteen percent reduction from baseline across the
18 board for all services, no variation there.

19 So this just puts in one table what our
20 goals, I think, should be. They're realistic, but
21 one might also think well, geez, we've already met
22 the national goals; therefore, we're in good shape,
23 but that's not the reality of what's occurring in
24 DOD.

1 The last four charts I'd like to talk to
2 you about briefly, shows what has happened over the
3 last four or five years with service specific
4 suicide rates among males aged 20 to 34, how this
5 compares with what a projected and realistic DOD
6 goal is, compared with what a national goal is.

7 Specifically for the Air Force, there has
8 been a lot of variability over the last -- from '87
9 to '92 and most recently, the rates are below what
10 are projected trendline would be to the end of the
11 century. And 1993 data would be below that line
12 also, so one could say the goal was met in the Air
13 Force.

14 Looking at Army males aged 20 to 34, it's
15 quite a different story. Whereas the last -- from
16 '80 to '90, the rate increased quite a bit and that
17 was due to quite a few number more suicides in 1990.

18 The trend is slowly going down, but they're a ways
19 from what a projected goal ought to be, I think.

20 Looking at Marine Corps males, again,
21 there's a lot of variability here. The Marine Corps
22 again has fewer cases than each of the other
23 services, but they are, at least from '90 to '92,
24 there was a downward trend. However, if you add '93

1 to that, the spike is way up around 20, so they
2 would be far from attaining a goal, at least midway
3 in the cycle to the end of the decade.

4 And then finally among Navy males aged 20
5 to 34, you can see that from '89 on and also into
6 '93, the rates have been slightly below a trend
7 towards the goal in the year 2000, and '93 would
8 continue that.

9 One might suggest from the data I presented
10 on the summary table among Air Force and Army
11 females, that we have other high risk groups other
12 than just males 20 to 34, that similar goals and
13 objectives broader than what DOD has adapted just
14 for males could be adapted or developed and adapted
15 for Air Force and Army females.

16 With that I close and will entertain any
17 questions. Thank you.

18 General.

19 GENERAL HOFFMAN: Did I understand from
20 looking at the data that a significant portion of
21 the suicide seems to be sort of in the transient
22 population in those when they're first brought in
23 and they're in training? Is that a place where you
24 would recommend that efforts primarily be focused,

1 if you were going to focus more in one place than
2 another?

3 COMMANDER HELMKAMP: Yes, sir. And what I
4 would use is the data that I have, which is
5 primarily descriptive and demographic, with JAG
6 Corps data.

7 Every suicide is investigated, I certainly
8 know in the Navy and Marine Corps and I think the
9 other services, to use profiles we developed. Is
10 there a marital problem, is there a work problem, a
11 finance problem, and use that satellite of
12 information along with what I've gathered to
13 pinpoint those specific groups like seaman recruits
14 and seaman apprentices.

15 That's a group that we can get to almost in
16 group in mass, to look at. We could do the same for
17 military police, for example, although they would
18 tend to be a little bit older and probably second
19 termers, but I would direct preventive efforts very
20 early on and to specific groups.

21 Yes, ma'am.

22 DR. STEVENS: Do you have any information
23 about the circumstances for these suicides? I ask
24 it because the data that you've presented, to me

1 doesn't tell you very much about how to go about a
2 preventive program.

3 COMMANDER HELMKAMP: No, and that's why I
4 suggest the JAG Corps data. It goes into a
5 tremendous amount of detail about familial
6 relationships, you know, whether it's between family
7 members or if there might be a homicide, suicide
8 involved or you know, again, family problems,
9 finance problems, administrative problems with their
10 job.

11 The DD-1300 in general doesn't provide that
12 information at all. Even prior to 1990 it didn't
13 provide that, so I think this type of data married
14 to any other medical legal data would be very, very
15 helpful, but I haven't taken that next step yet.

16 But there are certain working groups
17 within, I know the Bureau of Naval Personnel. that
18 does exactly that and we're working on combining our
19 efforts.

20 Yes, sir.

21 VOICE: Coast Guard. The new minor
22 denominator, is that regular active duty personnel
23 or is that a group of Reservists and National Guard
24 that might be temporary active?

1 COMMANDER HELMKAMP: If they were on active
2 duty, for example, Desert Storm, those 600,000
3 people, of which a certain group was Reserves called
4 to active duty, they would have been included in
5 this data base, but primarily over the thirteen year
6 period, it's just those regular on full time active
7 duty.

8 Yes, sir.

9 VOICE: The determination of
10 intentionality, accident versus self violence versus
11 other violence takes a judgment in both civilian and
12 military situations.

13 You've done a good job of sort of detailing
14 the process, the paperwork, et cetera, but knowing
15 what we know about the really bad job that goes on
16 about doing that in the civilian, I was wondering if
17 you would comment on do you think there's a
18 difference?

19 Certainly I don't think a difference in
20 proportioning out to accidental versus homicide
21 versus suicide will make up the difference between
22 your first several graphs, but certainly it may
23 contribute some. It sounds like you do a much more
24 in depth investigation in that information.

1 Does that play into the decision that it is
2 a suicide or is that decision made first and then an
3 investigation because that's probably a lot
4 different than the Justices of the Peace in rural
5 Texas that do the same kinds of things?

6 COMMANDER HELMKAMP: It probably is
7 different. By the time I can get the data it, the
8 decision is already made. But I think with fewer
9 cases in the military, we can be quite a bit more
10 specific. But then it's often a judgment call on
11 the medical officer's point of view.

12 I mean we had a case recently, I guess when
13 I was at BuMed a couple of weeks ago, where that
14 morning we got information on a fellow that took an
15 overdose of some pills and I think they were related
16 actually to prophylaxis for -- I don't recall
17 exactly the circumstances.

18 But gathering all the information together,
19 the medical officer was probably going to determine
20 this to be an accidental death, because the guy had
21 made a pact with his physician that I don't want to
22 commit suicide, you know, I have no intention of
23 doing it, yet some pills were available and he took
24 them.

1 Did he not know that these could kill him?

2 We'll never know, but that on the medical officer's
3 perspective was probably an accident. Many others
4 could argue it was a suicide, well intentioned. So
5 that may occur quite often in the military.

6 The paper that I provided you all on
7 Persian Gulf War casualties, if one was a student,
8 remembered the numbers that actually came out right
9 after the war, it differs from mine by about six or
10 seven.

11 Well, mine's based on a data source from
12 the medical perspective and DOD's actual release of
13 information was based on other sources of numbers,
14 so there's a disparity there and that can continue
15 and maybe exacerbate themselves, you know, in other
16 times.

17 But I think in general that we probably --
18 our numbers are, I would think, a little bit more
19 accurate than the civilian numbers and, in fact,
20 ours represent a full accounting of all deaths in
21 the military where NCA, just for example, is always
22 on an estimate basis for years and years and years,
23 and ours are true and hard numbers.

24 Dr. Kuller.

1 DR. KULLER: Yeah, a couple of questions.

2 One I think it's very nice data set and has some
3 potential important implications. First I think it
4 would be important to look at the contribution of
5 alcohol if you've looked at this, because in the
6 civilian sector alcohol is a major contributor to
7 suicide and the issue of depression, alcohol,
8 availability of a weapon and suicide is a very
9 common course.

10 So it might be worthwhile to look at
11 alcohol as well as other drugs, which may be used in
12 terms of a relationship to depression. It also
13 would be important to look back, I think, at the
14 medical records and see whether these suicides had
15 been previously identified with a variety of other
16 complaints, which might be a marker of depression.

17 Certainly, you're not going to be able to
18 solve the suicide problem by talking about problems
19 of marital discord and social problems because this
20 is so common again, that the ability -- and you just
21 can't change them.

22 We just can't change that much of society,
23 but we can identify, I think, premonitory phases of
24 people who might commit suicide and have that as a

1 warning system, especially if people are presenting
2 to the out-patient department medical command for
3 various symptomatology which might be a clue and
4 might require better education of your corpsmen, as
5 well as the physicians in recognizing the early
6 stages of depression and especially the implication
7 and association with alcohol or other drugs.

8 The other question, when you looked at the
9 -- if you can look at the firearms and deaths, how
10 many of the -- can you look at the relationships
11 between the firearms, which are basically related to
12 being issued and being related to being active
13 military and firearms which are essentially kept at
14 home, but have nothing to do with military?

15 Because again, one aspect of suicide has
16 been the fact of having firearms in the home and the
17 availability of the firearms. Now, again, there's
18 not much you can do about that except by education
19 and about recognition about the potential risks of
20 suicide associated with acute depression, because
21 that's the one area that you can make an impact.

22 And that is to influence the rapidly
23 changing behavior as an acute depression in which
24 somebody commits suicide as a response to a relative

1 acute change in depression and because the weapon is
2 available. And in that place, you have a potential
3 intervention as opposed to general social changes,
4 which are unlikely.

5 COMMANDER HELMKAMP: In relation to your
6 first point, there's a lot of work that has been
7 done by Rothberg and his colleagues with Army and
8 Air Force data on those that attempt suicides and
9 make gestures, with those that have completed it
10 and they compare many of the things that you've
11 talked about.

12 In relation to the second point, it would
13 be very interesting to know, for example, on the
14 Army and Air Force Military Police, you know, if
15 they are in fact allowed to take their weapons home
16 if they are on 24 hours call. How many of them use
17 their own -- their military weapons as a means to
18 kill themselves?

19 I don't know that, but certainly the JAG
20 Corps data would know that, I believe, so those are
21 interesting things which I will follow up on.

22 Yes, sir.

23 DR. ASCHER: Is there an insurance issue?
24 Does military insurance exclude it --

1 COMMANDER HELMKAMP: It's paid on every
2 death, I think.

3 DR. ASCHER: Does all civilian insurance --

4 COMMANDER HELMKAMP: Civilian, I don't
5 know. I don't know about civilian, but all military
6 insurance, I understand, is paid on, no matter what
7 --

8 DR. KULLER: It pays as long as you have
9 had your insurance for a certain number of years.

10 COMMANDER HELMKAMP: Yes.

11 MR. BRADY: Brady. I was wondering about
12 the same question about whether the services are all
13 equally likely to identify a death as suicide or are
14 some services less likely? Maybe you can review
15 that?

16 COMMANDER HELMKAMP: The data is submitted
17 through each casualty office within each of the
18 services and then it's collated and I don't think
19 there's quality review past the services. Each of
20 the services is responsible for their own QA. So to
21 answer that, I don't know if there are differences
22 and how one would term a death an accident or a
23 suicide. Good question.

24 Yes, sir.

1 MR. BRUNDEGE: Brundege. We've talked a
2 lot about the sources and the quality of the
3 numerators, but could you tell us how you estimated
4 the denominators?

5 So for instance, the trainee population
6 surged in the summer and it dropped in the winter
7 and if you used a single point in time as an
8 estimate of the total person-years exposure,
9 particularly say of the trainees, that could
10 significantly vary the denominator.

11 COMMANDER HELMKAMP: Like for -- the source
12 of the data is from the Defense Manpower Data Center
13 in Monterey and for each of the thirteen years, we
14 use the year end population, December 31st of each
15 year, and we made the assumption that attrition and
16 additions were evened out for each year and that's a
17 pretty broad assumption, particularly when there's a
18 lot of movement from being a trainee to their next
19 promotion or next duty station.

20 So I use the end point each year for that
21 and the data, you know, I was told was as accurate
22 as it could be from the Defense Manpower Data
23 Center. But I didn't do any -- and they have
24 various codes, the MOS' or occupational codes from

1 each of the services, they have secondary codes.
2 They also have DOD codes which are generic codes,
3 which all the service specific codes can feed into
4 for general comparisons.

5 Yes, sir.

6 MR. BRUNDEGE: It seems that might inflate
7 your estimate of trainee rates because that's
8 probably the lowest time of the year for trainees
9 entering service.

10 COMMANDER HELMKAMP: Yes, ma'am.

11 DR. BROOME: I'm not sure I heard the
12 answer to Dr. Kuller's question as to whether the
13 case investigations would find out whether these
14 folks had had prior contact with the medical system
15 or psychological help.

16 COMMANDER HELMKAMP: The medical, the
17 medical records should indicate that.

18 DR. BROOME: Okay.

19 COMMANDER HELMKAMP: Certainly I know
20 that's true for Navy personnel.

21 DR. BROOME: Two other questions. Will the
22 case investigations done by the JAG team be able to
23 ascertain issues related to sexual orientation?

24 COMMANDER HELMKAMP: I don't know.

1 GENERAL HOFFMAN: You don't plan to present
2 -- I mean, there's no active review of all the JAG's
3 records, and nobody's doing it, so we're talking
4 here in the hypothetical and in the hypothetical --

5 COMMANDER HELMKAMP: Not unless you direct
6 me to.

7 (Laughter.)

8 GENERAL HOFFMAN: In the hypothetical, on
9 every death there is, in fact, a criminal
10 investigation and all that can be discovered about
11 that person is discovered, so there's an in depth
12 investigation that the criminal investigation branch
13 of the services carries out.

14 VOICE: That's an ask and tell policy.

15 (Laughter.)

16 COMMANDER HELMKAMP: Well, I'd like to
17 present a challenge to Dr. Kuller and the Board.
18 I'm kind of a unique guy in DOD in my assignment
19 outside DOD to the CDC and the Public Health Service
20 and I've been doing this research more or less ad
21 hoc for the last three years, but I'd just love to
22 be told to do something or directed to do something,
23 such as get the JAG Corps data and marry with your
24 own.

1 Because I just go day to day; whatever I
2 want to do, I do. But I think with my detail to --

3 (Laughter.)

4 COMMANDER HELMKAMP: I'm probably opening
5 up a Pandora's box, but I'd love to do the -- answer
6 these type of questions and if it could be directed
7 by BuMed or others, I'd love to take the challenge.

8 DR. KULLER: I think the opportunity in
9 reality of doing a careful evaluation of whether
10 there is a preventive line in relationship to
11 suicide is very important and I'm not talking again,
12 not in generalities which are essentially non
13 preventable in our world, but in the issue of the
14 preventive components that may reduce the suicide
15 rates.

16 Not only -- I think they're very important
17 to the military, obviously, because this is still a
18 fairly big problem, but also may have some
19 implications in the entire, what you might call,
20 occupational setting, but certainly it would seem
21 useful to be able to determine whether there is a
22 point of prevention.

23 If none of these people had been seen by a
24 physician or a corpsman or had any symptomatology

1 for six months before hand, then you clearly know
2 that better education is probably not going to make
3 a huge difference.

4 On the other hand, if a lot of them have
5 been, then you may be able to identify some cluster
6 or some warning markers that may tell you when these
7 do present and somebody who also may have other
8 problems, alcohol problems, disciplinary problems,
9 et cetera, or anything else, that it is a warning
10 system to get some immediate care before there is a
11 catastrophe.

12 And so I think there is a potential. There
13 aren't very big numbers. You could probably do this
14 very nicely and get an answer. Maybe somebody has
15 done this already, I don't know.

16 VOICE: Air Force. It's a little bit old,
17 but SAC put quite an effort into suicide prevention
18 and the profile was a first term mail, security
19 police, who had recently been jilted by his girl
20 friend and they had an active program of education
21 and they were able to decrease their suicide rate by
22 educating supervisors, first line supervisors.

23 VOICE: It seems to me that, Jim, you have
24 two questions here and both of the questions have

1 implications that go far beyond just preventing
2 suicides and I think it's important to raise these
3 questions, especially in the context of having just
4 voted as a Board to form an injury sub-group.

5 And the first question is one of how do we
6 set our goals? What you said is that you've already
7 met your 2000 goals and so, in a sense, you've
8 recommended that we look at our goals towards making
9 improvement on what we witness in our population as
10 opposed to what the goals for the U.S. population as
11 a whole are.

12 So that's one set of questions that I think
13 is important and generic to all of the injury
14 problems that we encounter in the military. And the
15 other question is one of prevention and a lot of the
16 discussion has surrounded how do we prevent them and
17 what information do you have.

18 And I think that this is a good example of
19 the richness of the sources of data that we have and
20 the thoroughness with which you can attack the
21 problem. There's a lot of information out there,
22 but there are still a lot of questions about how
23 good is the data, what is the quality of the data,
24 what is the data that we need for this particular

1 problem?

2 And so what I'd like to say is, is that I'd
3 like to encourage the Board and others in the room
4 to look at this as a model for the way we approach
5 injuries and the type of data that's out there and
6 every time you see data, I think you will see that
7 there is an abundance of data available, as Jim has
8 shown us, with suicide and all of our injury
9 problems.

10 And the questions that we have to ask
11 ourself are one, what are our goals? Well, clearly
12 with suicides if we can prevent them, we'd like to
13 do it even if the goals are met.

14 And two, how do we use the resources that
15 we have to focus prevention strategies or research
16 and to prevent them. And I hear you asking that
17 question because you've been doing this on your own.
18 How do we get the resources focused on big problems
19 in order to get them solved?

20 DR. BROOME: I think you said that you also
21 were planning to or are in the middle of looking at
22 the homicide data and I guess I would assume that
23 you're focusing on the fairly striking observation
24 that in military females, what I would calculate

1 rapidly, they actually have a higher rate of
2 homicides than civilian females in striking contrast
3 to military males.

4 COMMANDER HELMKAMP: That's correct.
5 That's a major problem.

6 DR. BROOME: So I would think the Board
7 would be very interested in hearing further
8 discussion of that in the future.

9 COMMANDER HELMKAMP: That's the key finding
10 of my homicide research over the thirteen year
11 period was that women had a rate of about 1.3 times
12 higher than civilian females over the same time
13 period, and a majority of those women -- not a
14 majority, but a high percentage were either -- were
15 beaten and not killed with firearms or stabbing, but
16 they were beaten.

17 So that might suggest domestic dispute gone
18 bad, vis-a-vis O. J. Simpson, you know, but that is
19 a striking finding. I mean our women are getting
20 murdered at a higher rate than the civilian women.

21 VOICE: You mentioned one thing I found
22 interesting about a cluster of suicides and
23 certainly there's some data, for example, when a
24 high school student commits suicide.

1 COMMANDER HELMKAMP: Right.

2 VOICE: Or makes an attempt, there are a
3 variety of other potential attempts in that setting.
4 Are there more than one cluster here and is that
5 another potential prevention point, when one person
6 commits suicide, other people start making gestures
7 or make similar actions?

8 COMMANDER HELMKAMP: I don't know
9 specifically of, you know, of more clusters. We
10 could certainly look at that and are they mimic
11 suicides like you hear about in adolescents that do
12 that, that's something that certainly we could -- my
13 data would allow that to be done.

14 DR. KULLER: Well, thank you very much and
15 I think we'll break for lunch now and be back at
16 13:15.

17 (Whereupon at 12:07 o'clock p.m., a
18 luncheon recess was taken, to reconvene at 1:15
19 o'clock p.m., the same afternoon, in the same
20 place.)

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A F T E R N O O N S E S S I O N

7

(Time Noted: 1:20 p.m.)

8

DR. KULLER: We'll talk about something

9

called Gulf War Veterans Research.

10

COMMANDER GRAY: Could I have the first

11

slide?

12

Well, good afternoon, I'm here to talk

13

about our protocol, which has been funded by the

14

Department of Defense Health Affairs and to tell the

15

AFEB that we very much appreciate their help in

16

making this protocol a better series of

17

epidemiologic studies.

18

The studies I will discuss are the product

19

of a number of Federal and State organizations. Our

20

investigators include representatives from several

21

Navy Commands, the U.S. Army, the Department of

22

Veteran Affairs, and the University of California at

23

San Diego.

24

Additionally our work has been reviewed by,

1 as I mentioned, the members of this Board, the
2 Defense Science Board and investigators from the
3 Centers for Disease Control and Prevention.

4 I believe we have assembled one of the
5 strongest possible epidemiologic teams to conduct
6 these studies. Five of our investigators have
7 special credentials or experience in obscure
8 infectious diseases, several have conducted clinical
9 vaccine trials with more than 50,000 subjects.

10 Five of our collaborators have already
11 conducted epidemiologic investigations among Gulf
12 War veterans and tested several survey strategies
13 and instruments. Two of our scientists are Gulf War
14 veterans themselves and have detailed understanding
15 of the military units, terrains, environmental
16 threats and events of the war.

17 One investigator has already published
18 eight medical manuscripts regarding the Gulf War.
19 Two of our collaborators are civilian professors
20 with international credentials in epidemiology of
21 chronic disease and maternal child health.

22 Our team is additionally unique in that we
23 are very familiar with the soldiers and sailors who
24 fought the Gulf War and the data bases which record

1 their post war health experiences. In total, our
2 investigators have published over 750 peer review
3 manuscripts and books or journals.

4 Our studies are not designed to answer
5 every question regarding veterans of the Gulf War.
6 In fact, our studies are just one of approximately
7 20 projects now underway in the Department of
8 Defense and Veteran Affairs.

9 We have designed these projects to
10 economically build upon the survey strategies
11 already tested by the Navy, the Army and the
12 Department of Veteran Affairs in interviewing a high
13 risk and accessible population of Gulf War veterans
14 in a controlled fashion.

15 In addition, we will comprehensively study
16 the not as yet fully explored Department of Defense
17 medical data bases. In overview, our strategy is
18 three pronged. In our first study we will enroll
19 2,250 Seabees who remained on active duty.

20 Via personal interviews, we will
21 comprehensively collect data on numerous potential
22 risk factors and outcomes, looking for symptom
23 associations with service in the Gulf War.

24 In our second study, we will compare the

1 post war incidence of hospitalizations among the
2 large cohort of Gulf War veterans, 570,000, with
3 that of the random number of selected control sample
4 of 700,000. The hypothesis to be tested is that
5 there is no difference between these cohorts and the
6 adjusted incidence of serious illness among broad
7 categories as well as specific diagnoses.

8 Our third study, we will examine the
9 pregnancy hospitalization outcomes of the cohorts in
10 the second study since the end of the Gulf War. We
11 will test the hypothesis that there is no increase
12 in the incidence of fetal death, premature birth,
13 serious birth defects and neo-natal death.

14 Our first studies, study target Seabees who
15 served in the Gulf War and remain on active duty.
16 We have selected them because, number one, they are
17 accessible, we can find them and they are clustered
18 in Gulfport, Mississippi and Fort Wanne,
19 California.

20 Number two, they are stationed in the same
21 areas and perform the same task as reserve Seabees
22 who have reported high morbidity.

23 Number three, in contrast to the reserve
24 Seabees, they are relatively unbiased by clinical

1 job exposures, by civilian job exposures and
2 unbiased by close interactions with the press.

3 After informed consent is granted, we will
4 ask volunteers to donate blood for sera and whole
5 blood preservation. We will ask volunteers to
6 donate a urine specimen also for preservation. The
7 serum may be paired with sera collected before the
8 Gulf War and preserved in the DOD's HIV sera
9 repository.

10 As yet, no specific tasks have been planned
11 for the sera, whole blood or urine. Examples of
12 potential uses for these specimens include serologic
13 tests for leishmaniasis and hantaviruses, whole
14 blood tests for DNA markers and urine tests for
15 things such as adrenal insufficiency.

16 The identification and strategy for
17 evaluating specific tests will likely be developed
18 after the questionnaire data are evaluated. Due to
19 the high prevalence of respiratory and weakness
20 complaints captured from both the DOD's and VA's
21 Gulf War veteran registries, we have added two
22 physiologic tests to our Seabee study.

23 We plan to sample every tenth Seabee with a
24 computer driven spirometry test, which will adjust

1 readings such as forced vital capacity, forced
2 expiratory volume in one second, et cetera, for
3 various demographic risk factors, such as age, race,
4 sex and generate readouts in the percentage of
5 expected units.

6 We will also conduct hand grip strength
7 tests on every volunteer, using a hand dynamiter.
8 Both equipments can detect poor efforts or
9 malingering. I've listed here some of the risk
10 factors and outcomes that we'll be able to evaluate
11 with the questionnaire. We'll be able to look at
12 historical, environmental, medicinal, occupational,
13 geographic risk factors and also look at symptoms as
14 defined by working diagnosis of Gulf War Syndrome or
15 diagnoses that we develop ourselves.

16 We'll also be able to look at perceptions
17 regarding what might be causing their symptoms and
18 look at diagnosis they may have had as out-patients,
19 as well as hospitalizations. And finally, we've
20 added sections regarding birth outcomes.

21 Our questionnaire is now in the optical
22 scanner format and en route to the printers. We
23 have overhead examples of it, if you have any
24 questions. In our pilot study, we found that it

1 will take approximately 35 minutes for completion.

2 We have included a validated index self-
3 reporting symptom inventory called the Hopkins
4 Symptom Check List. This instrument contains 58
5 questions designed to quantify five symptom
6 dimensions, somatization, obsessive-compulsive
7 behavior or feelings, interpersonal sensitivity,
8 anxiety and depression.

9 We plan to use these symptoms, these
10 symptom dimensions in multivariate modeling for the
11 various outcomes. These outcomes will include the
12 DOD's working diagnosis for Gulf War Syndrome and
13 likely variations that we developed, as well as
14 screening outcomes for chronic fatigue syndrome and
15 post- traumatic distress disorder.

16 Our analyses will involve univariate
17 screening for the outcomes and then multivariate
18 modeling. The final models will likely lead to
19 additional questions and the need to conduct nested
20 case control studies of our population. We plan to
21 follow the cohorts through telephone interviews or
22 mailings for five years.

23 One of the concerns regarding this study is
24 whether our sample population represents the cohort

1 of Seabees, the entire cohort of Seabees who served
2 in the Gulf War.

3 You can see from this pie chart that only
4 about 65 percent of the active duty Gulf War Seabee
5 population remain on active duty in 1994. This
6 attrition may cause our sample population to be
7 biased towards the most health Gulf War veterans as
8 those with morbidity may have left the service.

9 Additionally, considering all Seabees on
10 active duty during the Gulf War, our study design
11 would draw only from the wedges at 11:00 and 7:00
12 o'clock, the Active duty Gulf War veterans those
13 that are still on active duty and the active non
14 Gulf War veterans who are still on active duty.

15 These wedges represent only about 40
16 percent of the entire cohort. We realize that we
17 may miss important outcome associations with Gulf
18 War service by so limiting our sample.

19 So we've decided in our investigator
20 meetings last month to design a validation study
21 among a random sample of all Seabees who served in
22 the Gulf War, who served during the Gulf War. This
23 study will involve an abbreviated form of our
24 questionnaire mailed to approximately 2,000

1 subjects.

2 Since the study involves persons who may no
3 longer be associated with the military, we are told
4 that we'll need OMB approval, which can take as long
5 as nine months. However, our collaborators at the
6 VA are seeking an exemption from this approval, this
7 necessary approval.

8 Our second study involves comparing active
9 duty personnel who were employed in the Gulf War
10 from August of '90 to July, '91 with 700,000 active
11 duty personnel who served at the same time, yet did
12 not deploy to the Gulf.

13 Our protocol mentions a random sample of
14 only 350,000. The 700 is a product of the Defense
15 Science Board -- or excuse me, the 570,000 is a
16 product of the Defense Science Board's
17 recommendations that we include all Gulf War
18 veterans. We plan again to follow these cohorts for
19 five years, until 1999.

20 We believe hospitalization is a good marker
21 for morbidity and that in contrast to out-patient, a
22 person who is hospitalized has to convince a
23 gatekeeper that they are ill enough to be so
24 examined.

1 Hence, we expect to thereby reduce bias,
2 which might be caused by personnel who are not truly
3 ill and intent upon seeking care for other purposes.

4 Since 1965 or so, the Navy has recorded
5 discharge diagnoses on hospitalized patients. Since
6 1989, these data have been standardized for all
7 services and captured for each Department of Defense
8 hospital throughout the world.

9 Each hospital discharge can have up to
10 eight different diagnoses recorded and they're all
11 recorded in the International Classification of
12 Diseases Clinical Modification 9 format. These
13 codes may be quite specific or combine to form large
14 categories.

15 We plan to compare the hospitalization
16 experience of the two cohorts for first large
17 categories and then smaller categories using
18 multivariate modeling.

19 Each hospitalization also has the
20 demographic information shown here on the left
21 column. We intend to use the data to search for
22 differences in adjusted rates of illness. Should we
23 identify interesting associations, we plan to obtain
24 additional data by linking SSNs to other data bases.

1

2 Some of the available external data are
3 listed here on the right column. We might also
4 contact the subjects with personal interviews and
5 additional questionnaires.

6

7 We realize that for this hospitalization
8 study with many study outcomes, we are likely to
9 find statistical associations that occur by chance
10 alone. Nevertheless, we intend to maintain the
11 philosophy that every outcome and risk factor is
12 worth examining.

13

14 We will screen for risk factor and outcome
15 associations in the first half of our data of
16 600,000 people. Univariate associations will lead
17 to final multivariate models.

18

19 Then we will validate the final
20 multivariate models in the second half of our data,
21 another 600,000. Thus, we will embrace Rothman's
22 philosophy of not adjusting for multiple comparisons
23 less we miss important associations.

24

25 This is Dr. Rothman's quote from a recent
26 article.

27

28 "A policy of not making adjustments for
29 multiple comparisons is preferable, because it will

1 lead to fewer errors of interpretation when the data
2 under evaluation are not random. Scientists should
3 not be so reluctant to explore leads that may turn
4 out to be wrong if they penalize themselves by
5 missing possible important findings."

6 So we'll have a check on spurious
7 associations. After multivariate models are
8 validated, we plan to interpret the models along
9 similar lines as that developed by the National
10 Academy of Science in interpreting the Agent Orange
11 data.

12 Here's a brief synopsis of how they
13 quantified their results or they valued them. They
14 looked for strength of statistical association, both
15 among -- both from Vietnam veterans and from
16 external studies of other population.

17 They made sure that there was a true
18 observed increase among the Vietnam veterans and
19 then they finally made sure that they had a
20 plausible biologic mechanism for causation before
21 they made any determinations and they had various
22 levels of association that they published in their
23 book.

24 One of the limitations we have with our

1 cohorts are again, their attrition rates. Although
2 we are fairly confident we can capture
3 hospitalizations while service persons are on active
4 duty, you can see here that we can project
5 considerable cohort losses or separation from
6 service each year.

7 As of this calendar year, only 54 percent
8 of the 579,000 regular active duty service members
9 remain on active duty. So one of the criticisms of
10 our hospitalization study is that veterans who
11 remain on active duty may represent the healthier
12 segment of our population and that ill service
13 members, particularly those ill from as yet
14 unidentified Gulf War exposure, may be more likely
15 to leave active duty and we would miss important
16 risk factor associations.

17 For this reasons, we are investigating
18 conducting a cohort study of veterans who separated
19 from active service and who live in California.
20 California has a non Federal hospitalization
21 registry which we plan to access.

22 Through collaboration with the Department
23 of Veteran Affairs, we plan to run our SSNs against
24 IRS address records and determine which veterans

1 live in California each year.

2 Similarly, by extracting annual California
3 hospitalization records with these SSNs, we can
4 again calculate rates and risk factors for separated
5 veterans. This will help us to determine if the
6 retired or separate veterans are more likely to be
7 hospitalized for certain diagnoses.

8 Another question that has been raised by
9 this body and others is that perhaps Gulf War
10 veterans still on active duty may be reluctant to be
11 hospitalized in the DOD system and go to systems
12 outside of the DOD. To check this hypothesis or
13 to test for this, we have decided that active duty
14 servicemen who are Gulf War veterans, although their
15 care is free and easily available, there is possibly
16 a small chance that they would have gone outside the
17 system, so we plan to examine both CHAMPUS and
18 Department of Veteran Affairs hospitalization
19 records and look at them in comparison with DOD
20 hospitalizations in a proportional distribution
21 model.

22 Another criticism of our study is that
23 perhaps we may miss important differences between
24 Gulf War veterans and controls if we compare only

1 hospitalizations.

2 To check this criticism, we're planning to
3 compare military disabilities or medical retirements
4 among the Gulf War veterans and controls. The
5 Department of Veteran Affairs plans to compare
6 mortality rates in a similar fashion, so there will
7 be several checks on this.

8 Our final study involves birth outcomes of
9 Gulf War veterans versus non Gulf War veterans, as
10 captured by the DOD hospitalization data base. This
11 will be performed by Lieutenant Colonel Defraites,
12 our collaborator at Walter Reed Army Institute of
13 Research.

14 The strategies will be similar to the
15 hospitalization study with the exceptions that when
16 a veteran is male, we will examine the pregnancy
17 outcome of his wife. Again, we will adjust for
18 various risk factors by multivariate modeling.

19 These studies too may lead to nested case
20 control studies, telephone interviews or mailings.
21 We plan to follow the cohorts until 1999 and we
22 again are concerned that the DOD hospitalization
23 experience may not represent that of the entire
24 cohort, so we will plan to conduct a validation

1 study.

2 In a fashion similar to that which the CDC
3 used in investigating Agent Orange exposure and
4 birth defects, we plan to identify a birth defect
5 registry where we might be able to determine if
6 separated Gulf War veteran offsprings are more
7 likely to suffer birth defects than there separated
8 controls.

9 Many of the sub-studies I mentioned
10 previously are due to the constructive criticism of
11 this Board and others. I want to summarize those
12 criticisms and review our response.

13 First, a couple of the AFEB members, and I
14 think it was reiterated here, stated that the
15 reputed Gulf War Syndrome was nothing new and not
16 worth studying.

17 Well, this may be true, however Congress,
18 the DOD and the veterans demand sound evidence for
19 such a conclusion and as a result of such demands, a
20 number of investigations are currently underway,
21 including our own.

22 Some of the Board members said we should
23 conduct an investigation -- we shouldn't conduct an
24 investigation until we had a case definition. I

1 hope that I have convinced you that we can perform
2 several studies with a number of various different
3 outcomes and still make some good headway regarding
4 personal interviews in our Seabee study.

5 Regarding healthy worker bias, which was a
6 comment by some members, the concept of studying
7 active duty service members -- the concept is that
8 studying active duty service members may miss those
9 who are ill and left service.

10 I hope that you'll agree with me that our
11 plans to conduct a mail survey among a random sample
12 of 2,000 Seabees, regardless of their current
13 service status, will help to examine this potential
14 bias. We also expect the registry studies among
15 separated service persons in California and the
16 birth defect registry study to help answer this
17 question.

18 Finally, the AFEB and others have suggested
19 that our cohorts may seek hospitalization outside
20 the DOD system and thus bias our results. We have
21 planned the CHAMPUS and VA proportional
22 hospitalization distribution studies to examine this
23 potential problem.

24 Regarding other criticism of our studies,

1 it is true that conducting interviews solely among
2 Seabees may miss important morbidity among units
3 suffering during the Gulf War and that our
4 hospitalization studies may fail to detect morbidity
5 in these other units.

6 We respond that our studies cannot answer
7 every question regarding the Gulf War and that
8 fortunately other groups have other studies
9 underway. For instance, the Department of Veteran
10 Affairs is planning a mass survey of some 50,000
11 Gulf War veterans, which will include physical exams
12 in a subset, possibly either a mailing or a
13 telephone interview.

14 Additionally, the CDC, in collaboration
15 with Public Health officials in the State of Iowa,
16 are planning an investigation in a similar fashion,
17 at least a telephone interview there.

18 Some have said that examining
19 hospitalizations alone may miss important out-
20 patient morbidity. We respond that we plan a
21 disability and medical retirement study to check
22 this potential bias and, again, that other groups
23 were relied upon to answer out-patient morbidity
24 questions.

1 Regarding the criticism that our
2 hospitalization study may yield spurious
3 associations by chance, we respond that our strategy
4 to divide the 1.2 million subjects into two groups,
5 one for hypothesis generating and one for validating
6 those hypotheses, will do much to reduce the chance
7 associations.

8 A final criticism is that the data obtained
9 by the Defense Management Data Center in Monterey
10 may be flawed. Perhaps some service persons have
11 been misclassified as having served in the Gulf who
12 actually were not there.

13 If this were true, many of the DOD's
14 studies are biased and hence, we'll plan to obtain
15 unit diaries of some large cohorts and try to
16 validate this data base.

17 Well, that pretty much concludes my
18 presentation. I'll be happy to field any questions
19 that you might have.

20 VOICE: Where is this master myriad of
21 studies that you referenced being coordinated, at
22 what level?

23 COMMANDER GRAY: We have the investigators
24 that you've seen in the protocol. Our work is

1 reviewed by our parent command which is an able
2 medical research and development command and also
3 monitored by the Department of Defense.

4 VOICE: I mean the next level up. You've
5 mentioned VA studies and clinical studies. Where
6 does that all come together, where does your study
7 fit into the grand scheme of those?

8 COMMANDER GRAY: Well, there's several
9 bodies, large bodies that are reviewing the
10 available research or the research that's ongoing.
11 Perhaps some of the members in this audience
12 represented can speak to that, but you know, I'm one
13 of twenty.

14 GENERAL HOFFMAN: Doug Hoffman. The
15 Department of Defense has enlisted the Institute of
16 Medicine as one of the oversight agencies and review
17 agencies for all of the studies related to the
18 Persian Gulf and the illnesses associated with that.

19 DR. ASCHER: I'm concerned that the Board
20 is seeing a very small piece of this and is being
21 brought in at a level that does not have the big
22 picture and I think we're completely blind as to the
23 overall scheme, and I don't know how we can comment
24 without the big picture, or if we're supposed to

1 comment.

2 MS. HANSON: In view of my perception that
3 most of the members of this Board do not believe
4 that there is such a thing as Gulf War Syndrome,
5 have you and your co-investigators spent some
6 serious time thinking about questions that can be
7 addressed with this study, that will lead to some
8 important questions to be answered that the Navy and
9 the military would like to have answered, but have
10 nothing to do with that Gulf War Syndrome?

11 COMMANDER GRAY: I think we can glean
12 additional information from these studies just by
13 combining the triservice hospitalization data. I
14 mean there's a lot of information we've not plumbed
15 with respect to rates, risk factors, et cetera.

16 So if you're asking me if these studies
17 will benefit us in addition to the Gulf War exposure
18 question, I would say yes, very much so.

19 We have tried to design these things with a
20 very open mind and to be very inclusive and that we
21 can, if there is a true association with Gulf War
22 experience, we may be able to detect it, but if
23 there are other explanations for some of the
24 morbidity reported by veterans, we may be able to

1 detect that as well.

2 MS. HANSON: I don't think you understood
3 my question.

4 COMMANDER GRAY: Okay.

5 MS. HANSON: Let me see if I can clarify
6 it. When you design such a study with so many
7 variables and so many people, what I'm asking you to
8 do is not go on a fishing expedition later, when
9 there is no Gulf War Syndrome.

10 But rather think now of exactly what
11 additional questions can be answered by proceeding
12 into this study and be careful that you've got all
13 the proper variables to answer other questions now.

14

15 Because just fishing through the data
16 later, will only allow you to discover that you
17 should have asked X or you should have done Y. But
18 if you can identify a dozen or whatever specific
19 questions that would benefit you, you would get
20 better material out of this whole process and learn
21 more.

22 COMMANDER GRAY: Okay. I think we've
23 developed some hypothesis, but I'm open to other
24 questions. Dr. Ascher.

1 DR. ASCHER: The reason I was asking before
2 was that we heard earlier and have heard in the past
3 this is a disease predominantly of Reservists and of
4 minor complaints with no evidence of any birth
5 defect outcome issue.

6 Now we hear of a study which is active duty
7 hospitalizations and birth defects. Now, if this is
8 all that's being done and all we're hearing, I would
9 be dead set against it.

10 If it fits into a bigger picture with a
11 rational and the other issues are covered by other
12 studies, I might support it, but I don't see that
13 this study tells me anything that I would like to
14 know about the syndrome from what we've heard
15 previously. It's an ancillary study at best.

16 COMMANDER GRAY: Well, I can't speak for
17 the other nineteen or so studies that are ongoing
18 and I would only say that they've been presented
19 exhaustively to both the Defense Science Board, the
20 NIH Panel and other bodies that I'm not prepared to
21 talk about.

22 We were asked that this body, since this
23 was an epidemiologic study, and perhaps one of the
24 larger in the DOD, if it would be -- if it wouldn't

1 be good, if the AFEB would help us make this study
2 the best we could, and I think that's why we -- why
3 you folks were asked to evaluate it.

4 I'm not sure what the general mandate is,
5 I'm not in a position to make those decisions.

6 DR. GWALTNEY: Two questions. Could you
7 give us an estimate of the cost of what your study
8 is going to be and would you state your primary
9 hypothesis, if you will?

10 COMMANDER GRAY: Okay. The cost of the
11 study, we received 725,000 this year. We project
12 roughly that, maybe 800,000 for next year and
13 perhaps the next several years.

14 DR. GWALTNEY: The total overhead.

15 COMMANDER GRAY: The total, it's probably
16 in excess of three million, maybe four. With
17 respect to the hypothesis, we laid those out. I
18 don't have them with me.

19 The hypothesis revolve around issues that
20 we would expect no increase or is there morbidity
21 associated with the Gulf War experience then
22 expected from a control population, whether that be
23 symptoms, whether that be hospitalizations, et
24 cetera, for birth outcomes, so that's our

1 fundamental hypothesis.

2 DR. GWALTNEY: What kind of effect size did
3 you use to -- what effect size are you looking for?

4 I mean those are two different end points, one
5 would be morbidity and the one hospitalization and
6 as has been pointed out, they're quite different.

7 You might have complaints that don't bring
8 you into the hospital. Those are going to have
9 different incidence rates and, therefore, you look
10 for different effect sizes and that's going to
11 determine your statistical power and those kinds of
12 things.

13 Do you have calculations as to what effect
14 size you look at, for example, in the minor
15 complaints or the kind that have really precipitated
16 this thing in the first place?

17 COMMANDER GRAY: Right. WE have some
18 estimations that we generated in the protocol which
19 we gave you some months ago, and I don't know those
20 off the top of my head, so I can't answer that
21 question. But we feel comfortable with that, that
22 we would be able to detect the differences with
23 those assumptions.

24 DR. GWALTNEY: Well, I'm not directing this

1 at you because you're just a spokesman, but I really
2 don't feel comfortable being able to pass judgment
3 on a \$3 million study when I don't know what effect
4 size you're looking at and what kind of power
5 calculations.

6 I mean, I think that should be presented in
7 this kind of a presentation, but not --

8 COMMANDER GRAY: Okay, I can actually do
9 that. I thought that perhaps, you know, -- I didn't
10 plan to do that today, but I certainly can the next
11 time around. I think if you'll note that we're
12 looking at the entire cohort, although 50 percent at
13 a time, it's a pretty darn good sample as far as the
14 hospitalization and birth outcomes go. The --

15 DR. GWALTNEY: Well, that's different from
16 having a priori hypothesis.

17 COMMANDER GRAY: That's true.

18 DR. GWALTNEY: And an effect size.

19 COMMANDER GRAY: That's true, that's true.

20 With our seabees study, we're limited in a number
21 of ways trying to be economical in this thing. We
22 try to identify cohorts who would be geographically
23 clustered and the seabees certainly are in contrast
24 to many other groups.

1 They're clustered in Gulfport, Mississippi
2 and Fort Wanneme, so although we're not sampling
3 tremendous other number of different occupational
4 groups, these for the reasons I mentioned
5 previously, we thought are a pretty good selection.

6 DR. KULLER: I think that some of the
7 criticisms or concerns that the Board had in the
8 letters that were sent to you, I think still remain.

9
10 I think the goals of the study, whether
11 there is a syndrome or not, the fact that you might
12 collect some useful data relating to
13 hospitalizations and some background
14 characteristics, if somebody wants to spend that
15 much money as long as it's not right out of my
16 pocket, although I guess indirectly it is, is
17 somebody else's concern since we're not being asked
18 to judge the scientific merit for awarding of a
19 grant.

20 But I am concerned over the fact that the
21 methodology that you propose to use is unlikely to
22 provide any answer, primarily because the selected
23 nature of staying in the service and the selective
24 nature of deciding who did or didn't go to Saudi

1 Arabia in the first place, is going to be
2 extraordinarily difficult to disentangle and
3 convince anybody either way.

4 What's going to happen and this happened in
5 Agent Orange, I can just tell you, if your study is
6 negative, the people are going to tell you that you
7 did the wrong study. If your study is positive,
8 they're going to tell you that you didn't deal with
9 the selection process of who went and how you
10 collected your data.

11 And so whatever way you -- whatever
12 happens, you're going to get roasted and I can tell
13 you right now, no matter what you do in this study,
14 the people who do it are going to be in deep trouble
15 in a short while, because either side is going to
16 essentially be very, very critical of the approach.

17 You've heard some of the criticisms over
18 the fact that you're not studying the Reservists,
19 that you're not studying minor symptomatology,
20 you're not studying out-patient data, you're not
21 really getting a hang on the people who might be
22 most effected.

23 On the other hand, you have the basic
24 problem that as happened in experiences in other

1 places, you're never really sure whether there is
2 selection bias associated with who did or didn't get
3 to Saudi Arabia which may, in the long run, affect
4 rates of hospitalizations.

5 Because rates of hospitalizations are very
6 strikingly affected by just things as cigarette
7 smoking, alcohol consumption, education even in the
8 military, as you well know and we've heard here and
9 where you are and what you are and what kind of work
10 you do. So these all become major, major problems.

11 We're not being asked to pass on the study,
12 but my suggestion to you would be, and it's only a
13 suggestion, is that you really need a hard nosed
14 group of epidemiologist and bio-statisticians who
15 should probably sit down with you and make sure that
16 the study is done in such a way that no matter what
17 the results is, at least people can say we can
18 understand the results and the findings you have no
19 matter what happens.

20 But I think right now, I'm just giving you
21 a little advice, essentially, and not telling you
22 what to do, I think right now you're in a situation
23 where you have the potential for doing a study which
24 can only have one result, and that result is trouble

1 to the people doing it.

2 COMMANDER GRAY: Okay. Well, I hear that
3 and I don't know what to do.

4 (Laughter.)

5 COMMANDER GRAY: I mean we have certain
6 constraints. For example, the populations we chose
7 to study are active duty, but that's because there
8 are certain other groups who are responsible for the
9 non active duty.

10 And we've tried to bring those other groups
11 in, but we feel like, with respect to the questions
12 out there and in an economical way, we've designed
13 the best study we can for the constraints. I think
14 we have some very good collaborators, Dr. Barrett
15 Conner is world famous in this field as a chronic
16 disease expert and has been very, very helpful.

17 And I wish that you were exposed to some of
18 the other groups doing work so that you would get
19 the big picture, but I can't organize that. I'm
20 sorry. Yes, Dr. Chin.

21 DR. CHIN: Just to follow up with Mike
22 Ascher's comments, is the Board to assume that all
23 of the other studies are non epidemiological?

24 COMMANDER GRAY: I don't think some of the

1 other studies are, at least the bigger ones,
2 particularly those from the VA, are far enough along
3 for you to review yet. Perhaps this is -- I think
4 Dr. Mazuki said this the other day, we're the first
5 one out of the box.

6 There are other studies en route, there's a
7 provisional bill I saw yesterday. I don't want to
8 mention the amount, but there's other interests and
9 other studies coming and I think like the Agent
10 Orange issue, before any conclusive decisions are
11 made regarding risk factors and other matters, that
12 experts will have to evaluate a number of different
13 studies to make conclusions.

14 So for that reason, I don't feel like we
15 have to have the last word on things.

16 General.

17 GENERAL HOFFMAN: Dr. Hoffman. If I could
18 get in an advertisement for the future, I'm not sure
19 to what extent it is every going to be possible to
20 go back with the Persian Gulf experience and put it
21 together the way that most of us would have it.

22 But I think what is pretty clear is that
23 what has happened in the Persian Gulf to some extent
24 or another was going to unfold for us in the future

1 and maybe it has already unfolded in Somalia and
2 sort of come and gone and that mogiditia of illness
3 hasn't presented itself yet, but it probably will in
4 the not too distant future.

5 There's other conflicts going on and
6 there's other conflicts coming. I think that the
7 Department found itself, as it has in the past, in
8 the very difficult position to be able to defend its
9 contention that all is well and there is no illness.

10 And, by the way, just sort of for the
11 record, the word the Department has picked is
12 illness, not syndrome, and actually, we spent a lot
13 of time with some dictionaries and some
14 philosophical discussions about the difference
15 between an illness and a syndrome, and we picked the
16 word illness because we think it's a better word
17 than syndrome.

18 It has less power and that's exactly what
19 we wanted. But I think that the Board should expect
20 and begin to anticipate that the Department will, in
21 fact, come forth and ask the Board to help the
22 Department plan the epidemiology in the evaluations
23 of future regional conflicts that we get involved
24 with and how we should approach them.

1 Because right now, we really are literally,
2 those of us that are in the middle of it, are
3 literally sort of dealing with a blank sheet of
4 paper. There's going to be a conflict someplace,
5 we're going to send in 100,000, 200,000, 300,000
6 people for a certain amount of time and they're
7 going to come back and then things are going to
8 begin to unravel.

9 What must we have collected in order to
10 know whether or not there's anything going on with
11 that group as compared to the people that did not
12 go? And we really don't have, this Board really has
13 the expertise, I think, to help guide us and help us
14 in the Department on how to do that.

15 And I want to really -- I'll put down the
16 marker for the Department, that we solicit your
17 assistance and your help in doing that in the
18 future, as soon as possible.

19 COLONEL CIRONE: My name is Colonel Cirone.
20 I'm with the Office of the Assistant Secretary of
21 Defense for Health Affairs and I just wanted to make
22 a couple of statements that I feel need to be put a
23 little bit into context.

24 Most of it has already been said by General

1 Hoffman, Colonel Tomlinson and Commander Gray, and I
2 appreciate those remarks and think they really
3 express what the Department has been going through.

4 And so I just want to summarize a little bit to
5 state that Health Affairs and Dr. Joseph hasn't
6 taken this issue lightly.

7 All of the issue that have been discussed
8 this morning and this afternoon, have been discussed
9 and agonized over.

10 He has not only discussed it within the
11 Department of Defense and within the Service
12 Surgeons Generals and their expertise, but he's gone
13 through the Department of Health & Human Services,
14 the VA, externally, through Defense Science Board,
15 which had a list of distinguished scientists on it
16 and through the Institute of Medicine, again, who
17 had a number of distinguished scientists who were
18 expert in their fields and with the intent, again,
19 to utilize this Board and to utilize the Institute
20 of Medicine.

21 It's an extremely complex issue, it's not
22 an easy issue. And I think that after agonizing
23 over this issue, Dr. Joseph, being in a leadership
24 position, had to do what he feels is correct and

1 this was his decision, to come forward with the
2 clinical evaluation protocol that was discussed this
3 morning by Colonel Tomlinson, and to do some
4 additional research in areas that need to be
5 explored more fully, one of which is Dr. Gray's
6 study.

7 And he feels that he made this decision
8 because in his mind, this was the right thing to do.

9 This is the way he felt that he had to resolve this
10 problem in order to respond to his constituency,
11 active duty soldiers and their families. Now, it
12 is a complex issue and that was his decision.

13 As far as the Armed Forces Epidemiology
14 Board is concerned, I know that he has great regard
15 for this Board. He's brought forward other
16 questions and, indeed, the Gray study, to get your
17 expertise, to ask you to evaluate it, to help us to
18 resolve some of these complex issues and to get your
19 input.

20 And that's the reason that it was presented
21 to the Board and we look forward to your
22 recommendations and your advice. And I think I
23 would again second what General Hoffman has
24 indicated, that we need to look for what we're going

1 to do in the future.

2 So we didn't plan this war to do an
3 epidemiological study. We planned the war to
4 respond to a crisis, but now we have an opportunity
5 to look at what we should do to the future, and
6 perhaps the Board will give us some assistance in
7 that regard.

8 I think that Dr. Joseph wanted to get the
9 input from this Board on a number of individual
10 issues, but he also on the advice of a number of
11 individuals, wanted to go external to the Board, to
12 go to other scientists, to go to two other
13 organizations that are not in any way affiliated
14 with the Department of Defense and that's the reason
15 that he went to NIH and to these two, et cetera.

16 And I'm sure that in the future he will
17 continue to come to the Board to ask for your
18 guidance and advice and other epidemiological
19 questions.

20 DR. STEVENS: Are you telling us to shut
21 up?

22 DR. CIRONE: No. That's not my intention,
23 but there's been a lot of discussion here and I did
24 want to put a little bit into perspective.

1 DR. KULLER: Did you expect -- I mean, one
2 of the concerns I have is that in hearing the
3 presentation today, and again, I'm not faulting
4 Commander Gray at all, but I'm getting -- do you
5 want us to advise you -- is this just an
6 informational piece or do you want advice?

7 I think the Board has provided some advice,
8 it's providing some advice today. The Board would
9 be glad to provide in writing to Dr. Gray or to Dr.
10 Joseph regarding this study and also what else is
11 going on in writing, if that's what you would like
12 or is this just informational to the Board and are
13 you just asking for response to information?

14 COLONEL CIRONE: To be honest with you, I
15 don't know what the question that came to the Board
16 was. I didn't see the format that it came in.

17 DR. ASCHER: Excuse me. We have no
18 question and this is an interesting structural issue
19 and you have also said however, you would welcome
20 recommendations, so we've got a question to you.

21 Could we then write a general
22 recommendation on this problem as a response to your
23 being here and not respond to a question? We have
24 no question before us.

1 COLONEL CIRONE: My gut feeling is that if
2 you don't have -- the Armed Forces Epidemiology
3 Board has existed for some period of time. I don't
4 know how you've responded to these types of
5 questions in the past or what the -- how the Board
6 has worked these various issues, and I would suggest
7 that you continue to respond as you have in the
8 past.

9 DR. ASCHER: In the past, we've responded
10 only to specific questions.

11 COLONEL PETERSON: Yeah, this is Colonel
12 Peterson.

13 The way this issue was addressed is one of
14 a variety of ways issues can be addressed to the
15 Board, and it was done on an informal basis for a
16 variety of reasons. A specific question in writing
17 was not addressed to the Board.

18 So I think because the issue was addressed
19 in the format of we would like some advice, here's
20 what we're going to do, we would like some advice so
21 we can produce the best product possible, I think we
22 have responded to that in an appropriate manner.

23 And the purpose of the presentation today
24 was to try to clarify what Commander Gray's

1 responses have been to what the Board members
2 provided in writing. If the services or DOD were to
3 ask us in writing to provide more specific guidance
4 or a group of this -- a sub-group of this Board to
5 act as oversight on this particular study, then I
6 think that becomes a different issue.

7 So we can really only respond to questions
8 in writing or to making suggestions, based on what
9 the services or Health Affairs comes to us with.
10 And that decision really, is made by the people who
11 are asking the question.

12 We cannot -- I mean, we can be proactive,
13 but I don't think it's the Board's position to
14 dictate to the services or Health Affairs further
15 than that.

16 COMMANDER GRAY: And let me say that we do
17 very much appreciate the comments of the AFEB and we
18 tried, we have adjusted the protocol accordingly
19 within the constraints we had. So I hope you saw
20 your handwork in the thing, particularly with the
21 validation studies. So thanks very much.

22 MS. HANSON: There's a difference between
23 our assisting you to make the single hypothesis,
24 that is your addressing of that hypothesis better.

1 However, and that's what Elizabeth Barrett Connor
2 could help you do as well. So your study could be
3 well designed.

4 But what I'm raising and I think what
5 General Hoffman has also raised is if the answer is
6 null, that is there is no Gulf War or whatever
7 illness or something else, then have you indeed
8 really specified in advance other hypotheses you are
9 going to study in this study, and have you done
10 power tests on those hypotheses.

11 And have you asked his question, will your
12 study answer his question? Will it tell you what
13 should be done for the next such conflict? In other
14 words, those are two separable, but similar
15 questions. What set of hypotheses are you asking
16 other than your primary hypothesis?

17 COMMANDER GRAY: We only address sample
18 size calculations on the primary hypothesis. We did
19 not do secondary tertiary hypotheses. Regarding the
20 second part of --

21 DR. HANSON: I would recommend that you do
22 that.

23 COMMANDER GRAY: Okay, thank you. I heard
24 that the second time now. Regarding, you know, what

1 to do in the future, I'm in no position to do that
2 sort of analysis. We're just trying to look at the
3 data that are available and to do a simple interview
4 study to try to answer some of the simple hypotheses
5 questions.

6 I wish we could just evaluate these
7 projects under that light and not see these as the
8 total answer for the Gulf War mystery illness. I
9 don't want that additional responsibility.

10 DR. KULLER: Dr. Woodward, did you have a
11 question?

12 DR. WOODWARD: Yes, Mr. Chairman, I'm going
13 to break a promise to myself. I promised myself to
14 shut up.

15 (Laughter.)

16 DR. WOODWARD: My comments will not take
17 sides because I wouldn't have it --

18 (Laughter.)

19 DR. WOODWARD: A little bit of historical
20 reference of this Board. It was Dr. Paul Demson who
21 recommended it, recommended and the Board
22 practically directed AFEB to formulate the
23 guidelines, the problems, environmental,
24 epidemiological, causal, everything of every

1 potential trouble spot in the world where our nation
2 might become involved.

3 And the problems by this area in that work,
4 presented it to the Board for over seven years and,
5 Mike, you're shaking your head and it was my opinion
6 that that was a very valuable document and
7 presentation.

8 All I'm hearing is there is an effort to
9 learn how to collect information, be prepared with
10 when we go on, but you have to analyze it after you
11 came out. It costs money.

12 DR. STEVENS: I had a question. It's not
13 clear to me what proportion of the cases that are
14 being called Gulf War Syndrome presented at some
15 point with an illness that caused hospitalization.

16 I think to me that hospital study has
17 already been criticized and it sounds to me as if a
18 priori, you're setting out on a study to look at an
19 end point which has no relationship to what's being
20 called Gulf War Syndrome.

21 And if that's the case, then you're
22 launching into something that is predicted to be
23 nothing, end up with nothing.

24 COMMANDER GRAY: But I think we're

1 anticipating --

2 DR. STEVENS: And not answer a question
3 related to Gulf War Syndrome and that, I think, is
4 where you're going to get yourself into trouble.

5 COMMANDER GRAY: Yeah. The data are
6 captured. You know, we don't have to do any active
7 collection. Our thinking was that if this continues
8 on in its Public Health interest, as the Agent
9 Orange issue did, then there will be many, many
10 questions regarding health care benefits to people
11 with various different hospitalizations and
12 diagnoses.

13 In anticipation of that, we have designed
14 this study to see if there's a difference between
15 the Gulf War experience and those that do not go in
16 the Gulf War. It's really not that expensive. It's
17 labor intensive, but not that expensive.

18 One would hypothesize that if there was
19 something that in the environmental exposure to Gulf
20 War veterans that causes out-patient morbidity, that
21 you would perhaps see a significant blip in the in-
22 patient morbidity as well, and so we're testing for
23 that at the same time.

24 DR. KULLER: I think what's confusing

1 people here is the idea that you're trying to find
2 something called Gulf War Illness. Your study has
3 absolutely nothing to do with that, but the study
4 basically is asking a question about whether people
5 who served in the Gulf War have a higher
6 hospitalization or morbidity rate, as opposed to
7 people who didn't.

8 My concern and I have nothing wrong with
9 that study. I think, you know, as somebody said, it
10 might not be bad as a model. My concern is again,
11 and I'll repeat that, is somebody who was involved
12 from day one in the problem of Agent Orange and all
13 the studies that got involved in over -- because I
14 happened to make a mistake of being involved in the
15 very first study for \$20,000 and before you turned
16 around, they were going to give you the world.

17 But the reality is that those studies went
18 through a lot of critical reviews, a lot of changes.
19 CDC did a superb job finally of cleaning out a lot
20 of big problems and a lot of very bad studies that
21 went along the way.

22 And I think, when we talk about the
23 historical perspective of these studies, one has to
24 go back and see what happened in the past with the

1 Agent Orange or Vietnam, because CDC finally did, as
2 you know, what you're trying to do, did a study
3 which is called Vietnam Experience.

4 They finally threw in the sponge and said
5 we can't study Agent Orange because we can't measure
6 it, but we can measure people who went to Vietnam
7 and who didn't. We can Vietnam experience, at
8 least, and see what happens in terms of various
9 diseases.

10 But they dealt with the basic problem of
11 case ascertainment, hospitalization rates and the
12 problems of selection bias about who did and who
13 didn't go to Vietnam. And all I'm saying is to you
14 now and again it's advice because we're not being
15 asked the specific question is, you can do the
16 study, but do it in such a way that no matter what
17 your result is, you're not going to be criticized
18 for doing a faulty study.

19 Because if you do it and you're criticized
20 for doing a faulty study, then the only people who
21 basically wind up on the wrong end of the stick are
22 the investigators and that happened in Agent Orange
23 and it's going to happen here again.

24 COMMANDER GRAY: Dr. Ascher.

1 DR. ASCHER: Dr. Woodward talks to me
2 sometimes too and the other thing he said was, as in
3 the case of the HIV problem in '85, which was coming
4 from all different directions and going all
5 different directions, that the Board did sort of
6 focus that for the services and get that under one
7 hat and bring it all together.

8 And one of my perceptions here is this is
9 the National Academy, NIH, Letterburg, all the
10 people out in different directions and that's
11 because it's had to happen fast and there's been
12 really no overall planning.

13 And I think if we were to make a
14 recommendation informally, you need an overall
15 planning committee for this that is independent,
16 that has to be independent of both financial
17 conflicts of interest, as I mentioned earlier, and
18 of any other constraints in terms of turf.

19 Because right now, every player has got
20 turf, and unless you use the Board as it has
21 functioned in the past to be the mediator of these
22 issues, we're still going to have a mess. And that
23 would be a recommendation that we would offer.

24 COMMANDER GRAY: Well, who am I to accept

1 or reject such a recommendation.

2 (Laughter.)

3 COMMANDER GRAY: I'm really open to
4 criticism, because I really genuinely -- we tried to
5 make this as clean and as uncriticizable as
6 possible, so I mean we had a number of people that
7 said it's not worth doing because there's no Gulf
8 War Syndrome, but if you have suggestions how we can
9 prove this, let me try to go back and we'll make
10 some adjustments.

11 I'm very open and if they even want to
12 appoint a committee, that's fine on my account.

13 DR. ASCHER: I'm talking to the Assistant
14 Secretary, I'm not talking to you. It's not at your
15 level that the problem is.

16 COMMANDER GRAY: You're right. Thank you
17 very much.

18 DR. KULLER: One more comment and then I
19 think we'll go on.

20 COMMANDER GRAY: Yes.

21 VOICE: I just wanted, Commander Gray, to
22 speak in some support of what you're saying here. I
23 think you do have a hypothesis. I think whether
24 this group is sick or not are the measures available

1 and the setting of a syndrome that we all agree we
2 can't quite define, is worthwhile doing. And so I'm
3 supportive of it.

4 I can concerned, as others, about some of
5 the selection bias issues that have been discussed
6 and I'm not sure I've heard from your brief
7 presentation whether some of these extra sub-studies
8 are going to deal with that.

9 The third point really is for Dr. Joseph, I
10 guess, and I think you're hearing from a number of
11 people who are his representatives that are here,
12 because there's a lot of studies going on and they
13 don't seem coordinated.

14 They may be overlapping, they may be using
15 different methods, but that's not your problem, but
16 it has to be someone's problem centrally to
17 coordinate these in a way, so we learn more about
18 what's going on here.

19 DR. WOODWARD: Mr. Chairman, this is very
20 simple, that the ranch hand study involved a limited
21 number of men, as I recall, 1,500. And that saved
22 us a heck of a lot of problems and dollars and there
23 must be something in this study that can be pulled
24 out and not be broad and could give us something.

1 COMMANDER GRAY: Thank you very much.

2 DR. KULLER: Thank you.

3 (Applause.)

4 DR. KULLER: We'll now talk about the U.S.
5 Air Force Office for Prevention and Health Services
6 Assessment Program. Colonel Wright.

7 COLONEL WRIGHT: My name is James Wright,
8 Jim Wright. I'm the Epidemiology Division at Brooks
9 Air Force Base, which is a part of the Human Systems
10 Center and I'm here today to talk about the Office
11 for Prevention and Health Services Assessment, which
12 is a new organization that the Air Force is trying
13 to build right now.

14 Can you hear me now? Can I have the
15 second slide.

16 But first let me take you back about three
17 years in the Air Force Surgeon General's Office
18 where we realized we were becoming involved in some
19 pretty big projects right over the horizon or right
20 on our doorstep at that point, such as Health People
21 2000 where the National Public Health Service wanted
22 to set national health codes for the population and
23 make sure we met them by 2000. The Department of
24 Defense was going to set DOD health codes and do the

1 same thing.

2 Managed care. We're getting into the
3 managed care arena where we actually have to try to
4 utilize our health resources to the maximum and try
5 to use tri-care in various ways to actually provide
6 all our beneficiaries the proper amount of medical
7 care in the most effective or cost effective manner.

8 And of course to put prevention into
9 practice, which Colonel Parkinson has mentioned
10 already today was right around the horizon at that
11 point. Fortunately, it was delayed a little bit,
12 but we are getting into that. At the present time,
13 we have to implement that in the very near future.

14 And we had a lot of health promotion and
15 wellness programs out in the Air Force, but we
16 needed to start evaluating how effective they were,
17 which ones were working and which ones weren't and
18 get some control over all the different ones that
19 were springing up throughout the Air Force.

20 May I have the next slide, please.

21 Unfortunately, when we tried to do that, we
22 found out that we had some real serious problems.
23 We didn't have any idea about the basic help data
24 that we really needed. We didn't really know what

1 the health status of our beneficiary population was.

2 That was unknown to us. We didn't have the basic
3 data.

4 And if you don't know what the health
5 status of the population is, you of course can't
6 figure out the health needs of the population. And
7 if you don't know the health needs, you can't figure
8 out what required health resources you have to have
9 to fulfill those needs.

10 So we needed some basic information about
11 the health status, health needs, and required health
12 resources of our population.

13 On the preventive side, we realized that we
14 were in the same boat, we didn't know the preventive
15 services needs for the health population, because we
16 didn't know the health status. Therefore, we didn't
17 know what the risk factors were, or what the health
18 services or preventive services needs were.

19 We didn't know what we were doing out there
20 in preventive services, so we didn't know what was
21 available and we didn't know how much of what was
22 available was properly being utilized.

23 As far as the health promotion programs, we
24 just couldn't calculate them. Most of them had

1 data, but it wasn't centralized, it wasn't
2 computerized and it wasn't forwarded to us to really
3 make any heads or tails of it, so we really couldn't
4 calculate how effective the various health promotion
5 programs were.

6 If I could have the next slide. So what we
7 found out was that existent data bases to provide
8 this information simply were not sufficient. I
9 mean, we had lots of data bases out there, but they
10 just weren't sufficient to provide the information
11 we needed.

12 We did have lots of in-patient numerator
13 data. We knew how many were hospitalized for, you
14 know, heart attacks, for the various kinds of
15 cancer, and that sort of thing, but we didn't have
16 any good denominator data to compare rates with
17 those particular things.

18 And as far as out-patient treatment data,
19 we just didn't have anything. I mean, the
20 facilities might know, as somebody mentioned before,
21 how many suture kits they used and that sort of
22 thing, but they didn't know what they were used for,
23 how many people were coming in for what diagnosis
24 and what the providers were treating these people

1 for, how effective we were utilizing our providers
2 on medical resources.

3 Now, DEERS, of course, has lots of
4 demographic data. They can tell you how many E5s
5 and Air Force they have and where they're located
6 and which commands they're located in, what their
7 ages are and that sort of thing, how many are male,
8 how many are female, but that wasn't linked to the
9 medical data, so it really didn't help us a whole
10 lot at that point.

11 We had lots of demographic and medical
12 data, but they weren't linked and they really
13 weren't the right kind of data, at the time, to give
14 us the information we really, absolutely had to have
15 to get these programs going and to monitor the
16 programs.

17 And as I mentioned, wellness and health
18 promotion data was not centralized, computerized, et
19 cetera.

20 Next slide, please.

21 On the prevention side, we also figured out
22 that we'd known this for a long time, but it became
23 more apparent that we really needed some of this.
24 There was no central data library for prevention and

1 health service.

2 We really didn't have a central location we
3 could go to get all the prevention information we
4 needed or all the health services, the managed care
5 type data that we were going to need in the future
6 and we had no repository for the various abstracts
7 and so forth that we really needed.

8 We had to go to various libraries and that
9 sort of thing to get them and we really didn't have
10 any organization that could provide rapid responses
11 to some of the questions that were coming up to the
12 Surgeon General's Office and other organizations
13 that needed rapid response.

14 And the data bases were around here, but
15 nobody could really provide the rapid response
16 because they couldn't get access to the data bases,
17 didn't know how to use them, and they couldn't
18 provide a linkage between data bases to get the
19 information.

20 Next slide.

21 So we realized there was a big problem and
22 we, for two years, tried to solve it by getting
23 various organizations to work together and to, you
24 know, double half, to get people doing full time

1 jobs, to do additional jobs to figure out how we
2 could do this in-house without additional resource,
3 without additional manpower.

4 We finally came to the realization that
5 that just wasn't possible. To get this information,
6 you really needed an organization dedicated to that
7 and we're going to have to put up some resources to
8 get it.

9 So in June of '93, this was presented to
10 the Surgeon General who approved the establishment
11 of the Office for Prevention and Health Services
12 Assessment or OPHSA, for short.

13 And the name, I know, is long and it sounds
14 like a committee name, but it does cover what the
15 organization will do. The charter is more broad
16 than just prevention or preventive services. It is
17 going to evaluate health services, evaluate health
18 resources and health resource utilization. That's
19 what the health services assessment part of the name
20 comes into being.

21 So the name is appropriate to our
22 organization, even though it may not sound
23 particularly good. OPHSA is kind of -- you know, it
24 could be misinterpreted as UPSHA and a few other

1 things, so we would have preferred it perhaps a
2 shorter, more catchy name, but this does cover what
3 the organization will do.

4 If I could have the next slide.

5 The mission of the organization is pretty
6 straight forward. It's to find operational
7 commanders, that is line commanders, flying
8 commanders and managers of the health programs,
9 directors of base medical services, Surgeon General,
10 et cetera. We'd improve capabilities to make
11 evidence based decisions.

12 I mean they've got to make the decisions
13 any way, they're going to have to do that whether
14 they want to or not. The decisions have to be made.

15 What we want to be able to do is give them some
16 information so that they can make rational decisions
17 based on the evidence.

18 They really need that information to make
19 good decisions and back up their decisions and
20 that's what the charter of our organization is, to
21 provide them that information and capability to do
22 that, and to provide the capability to measure the
23 impact of interventions they implement, such as
24 smoking cessation programs, that sort of thing.

1 Once they implement an intervention
2 program, we want to be able to provide them the
3 baseline data, what it is right there, what happens
4 when they implement the program and, you know, to
5 monitor it throughout its lifetime, and hopefully,
6 to build in an evaluation process into the program
7 before it's implemented so that you can do that very
8 easily.

9 If I could get the next slide.

10 The goals of the organization are pretty
11 straight forward, prevent the premature onset of
12 disease and disability, improve operational
13 readiness, to enhance the effective -- excuse me,
14 the efficient utilization of health services or
15 medical resources and to reduce health care costs.

16 And we feel that if we do the first three,
17 the fourth one will kind of follow naturally, so
18 it's -- that one would just come along. We don't
19 really have to stress that. Originally, we'll do
20 the first three to start with.

21 Next slide, please.

22 The objectives are to determine the
23 prevention and health services needs of the Air
24 Force or Air Force beneficiary population, to

1 improve the delivery of preventive and health
2 services to our beneficiary population.

3 To evaluate the effectiveness of prevention
4 programs and other intervention programs and health
5 services programs. To develop prevention
6 guidelines and to maximize the cost effective
7 utilization of health resources.

8 And we also, as one of the things we'll be
9 involved in to a certain extent, will be to monitor
10 prevention and health research. That doesn't mean
11 we'll do the research, it just means we'll monitor
12 the people that are doing it, to monitor the
13 resources and make sure that it's kind of done the
14 correct way or that we at least know what's going on
15 and try to make sure it's cost effective and that
16 sort of thing.

17 Some of the strategic subject areas will
18 be, of course, clinical preventive services because
19 we're in prevention. We'll do special studies on
20 pretty much anything the customer wants and that
21 sort of thing. We'll be involved in mission
22 readiness and deployment, helping to do some of the
23 things that I think General Hoffman has mentioned
24 several times and other people have too.

1 We'd like to get involved in helping
2 determine what the deployment, pre-deployment
3 information and various surveillance activities and
4 medical data that you need to collect.

5 What you need to collect while you're
6 deployed and what you need to collect when you come
7 back, what kind of studies, screening and that sort
8 of thing will be involved in deployments to various
9 areas of the world.

10 Of course, fitness and injury prevention,
11 the Air Force, as you know, is involved in the cycle
12 ergometry program, which I believe Colonel Parkinson
13 will discuss later, and of course we need to be
14 involved in health emotion and occupational
15 medicine, all disease surveillance, not just
16 specific diseases.

17 But essentially all disease and injury and
18 disability surveillance and quality assurance
19 research outcome and managed care which apparently,
20 not apparently, but is becoming one of our biggest
21 customers, even before we really get formed. That's
22 one of our biggest is the managed care in Region 6,
23 has come to us for several projects already.

24 And we need to develop data bases, monitor

1 data bases, get access to data bases and link
2 various data bases to get the information.

3 Some of the characteristics of the
4 organization we like to make sure that it has from
5 the very start is it will be customer driver. The
6 organization will not be driven by what we want to
7 do, but what the customer needs.

8 Customers will come to the organization,
9 give a need, we will then try to fulfill the need
10 for that information or that data. It will of
11 course be a center of excellence or as close as we
12 can make it.

13 It will bring together the previously
14 scattered preventive medicine activities in the air
15 Force, not right away, but down the road we'll draw
16 some of the preventive medicine activities like the
17 epidemiology division and some other things may
18 eventually be merged into this organization.

19 Right now, they're separate.

20 And will produce consultation analysis of
21 various different products. And one of the things
22 we wanted to make sure right away that we followed
23 quality management, quality Air Force management or
24 TQM as most people know it by, and we use integrated

1 product teams, which is, you know, the team approach
2 as opposed to one individual doing something.

3 We'll get a team together on each project
4 and try to make sure it's a team project and get it
5 through that way and we use TQM management from the
6 very start. This will be unique in that this will
7 be one of the few military organizations that can
8 use TQM from the very start, instead of trying to
9 impose it over the normal Air Force's bureaucracy,
10 which doesn't seem to work very well.

11 Where to put the organization was very
12 simple, because Human Systems Center is located in
13 San Antonio, Texas, and it has the epidemiology
14 division, the occupational environmental health lab.

15 Kelly has a very large occupational medicine
16 activity.

17 The School of Aerospace Medicine is part of
18 HSC. There are various preventative and
19 occupational medicine activities already in San
20 Antonio, so it made perfect sense to put it in Human
21 Systems Center at Brooks Air Force Base.

22 So it will be located at Brooks and it will
23 be part of the Armstrong Laboratory, which is one of
24 the Air Force's four super labs and will be a

1 directorate of the Armstrong Laboratory. It will be
2 funded directly by the Surgeon General, at least for
3 the first few years and it will use operational
4 funds.

5 It will not use medical research funds, but
6 it will be patient activity or patient operation
7 funds, which is a very big coup for the organization
8 to actually get that kind of funding.

9 The eventual size of our organization will
10 be twelve officers, eighteen enlisted and seventeen
11 civilian positions. The civilians will be either
12 Civil Service or contract civilians and we haven't
13 figured out exactly what the mix would be on the
14 civilian/Civil Service/contract, because a lot of
15 things are going on in the Air Force with hiring
16 freezes for civilians, ceiling for civilian hires
17 and all that sort of thing, but we have to be
18 flexible and come up with a mix about the time we
19 need the people.

20 This is an organizational chart of the
21 organization. As you can see, it will be divided
22 into four sections or four divisions. We have the
23 clinical preventive services division, which will do
24 disease surveillance, clinical preventive services

1 guidelines and the usual thing that you think of
2 that preventive medicine and occupational medicine
3 would do.

4 You'll have the information analysis
5 division which will function pretty much as an
6 information analysis center and will mostly be
7 contract, so that we have flexibility so that we can
8 hire lots of people for big projects and let them go
9 when we get small projects and have the flexibility
10 that a contractor has, that the Civil Service or an
11 active duty organization does not have.

12 This will provide basic information. It
13 will be like the large data bank that will have
14 access for very -- data bases and we'll utilize
15 those data bases to provide information. It will
16 kind of like a big library of data base and data
17 information and we'll have external customers, but
18 it also will mainly be a customer to these two
19 organizations.

20 And the studies and analysis division will
21 be just what it says, they'll help design studies,
22 help analyze studies for themselves and for
23 customers and will actually conduct studies, various
24 studies that we need to do to get information for

1 the customers.

2 And then the administrative support will
3 just provide administrative support to all three
4 other divisions, because you have to have
5 administrative support to keep things working.

6 In reality, as I mentioned, the various
7 projects will be controlled by teams and right now
8 we already have about ten or eleven integrated
9 product teams for these particular projects or
10 topics. Clinical preventive services, of course, we
11 have to have a team for.

12 Fitness and injury, we need a team for.
13 Medical readiness you need a team, et cetera, et
14 cetera. People from the various divisions will be
15 placed on a team and, of course they'll be on more
16 than one team and people from outside the
17 organization will also be asked to be put on a team
18 with their expert as needed, as will contract
19 personnel and that sort of thing.

20 And then the team will work together and
21 then peruse the product, one of these products and
22 the products will be consultation. The usual
23 products you get out of research or information
24 analysis type of consultation, organization.

1 Consultation is written or oral. You get
2 search and summary reports, you'll get technical
3 reports, special study reports and technical
4 conferences, which we hope to utilize quite
5 effectively that will be bringing the experts in to
6 a big conference to determine how best to answer the
7 question and what kind of studies you need to answer
8 the question.

9 Okay. As far as the staffing, as I
10 mentioned we're supposed to end up with a total of
11 37 people, but we're early in the program so right
12 now we have four officers currently on board,
13 there's two preventive medicine officers, two
14 preventive medicine physicians, one medical service
15 corps officer and one Military Public Health
16 Officer.

17 We hope to have another four officers
18 filled by the end of the summer and, of course,
19 there's four of us doing other jobs that are working
20 most of our time on OPHSA or all of our time on
21 OPHSA.

22 Enlisted, it's going to take a while to get
23 those people because they were put on the books for
24 FY'95 and our military manpower center really won't

1 give you the enlisted people until they're actually
2 on the books.

3 And we're having a problem with the
4 civilians, because as I mentioned, hiring freezes
5 and ceilings and that sort of thing, plus they don't
6 officially come on the books until 1 October, '94.

7 May I have the next one.

8 So what we're doing right now, is we do
9 have a lot of projects we're involved in. I'm going
10 to go over some of those in just a minute, but to
11 actually accomplish those projects, the organization
12 with only four people, there are a lot of things
13 that we haven't -- we haven't been able to get a lot
14 of people on board yet.

15 All staff is double assigned to AOE, the
16 epidemiology division, until they officially come on
17 board on 1 October. We do have an inter-agency
18 agreement with the Centers for Disease Control in
19 that we can use their subcontractors to actually do
20 projects for us.

21 We'll give the CDC money. They'll give the
22 money to the contractor and then the contractor will
23 do the project and produce the products that we ask
24 for. We're working with the environmental section

1 of CDC because they seem to have the contractors
2 with task order of contracts that most suited our
3 needs for the present time.

4 We'll issue Form 9s, which is a small
5 contract like the Air Force has for small task
6 orders and we're getting our computer support from
7 the Air Force Medical Support Agency, which is the
8 big airport data base, medical data base in San
9 Antonio, at Brooks right across the street from it.

10 And we get our administrative support from
11 the Armstrong Laboratory.

12 We will get a contract eventually. As you
13 know, in the military it takes at least 18 months,
14 sometimes up to three years to actually get a
15 contract written, statement of work written through
16 contracting and get it on the street, get the bids
17 back and get it awarded.

18 It's no simple task, but we will eventually
19 get a contract to support the Information Analysis
20 Center, but it's probably going to take us about 18
21 months to do that, so we have to use the CDC and
22 various agreements and other task order contracts
23 and to enter them to get any work done.

24 Let me just take a few minutes. I know

1 we're running late because of all the interesting
2 comments on the previous presentation, but I'd like
3 to go over some of the projects we're involved in
4 right now. This is just a list of some of them.

5 If I could have the next slide, that's the
6 list of the rest of them. If I could have the next
7 slide, I'll go into some of them very quickly.

8 As I mentioned, we have to have a customer
9 and our customer for this was Medical Region 6 and
10 then later Medical Region 4 came on board when they
11 heard about this particular project.

12 Medical Region 6 will have to enroll all
13 their beneficiaries into medical care, tri-care, and
14 what they need to do is to find some kind of
15 questionnaire or form that when they enroll these
16 people into their medical system, they can find out
17 some basic information.

18 The basic information they would like to
19 know is what the past medical problems of that
20 particular enrollee is, what his current health
21 status is, including current health, you know, risk,
22 behavioral modification risk type things, and
23 identify the preventive services needs, whether the
24 person needs smoking intervention, doctor

1 intervention, that sort of thing.

2 And to identify the large resource users
3 that will require case management. People like
4 insulin dependent diabetics or people who have had
5 previous heart attack or that sort of thing, will
6 probably be better served if you actually assign
7 them to a case manager, who can manage their care
8 and make sure that they're taken care of, so that
9 you can prevent any serious disabilities by taking
10 care of the minor ones as they come up. So they'll
11 be more intensely monitored and more intensely
12 surveyed.

13 And also to determine the appropriate
14 primary provider that individual needs to be
15 assigned to, internist, pediatrician, general
16 medical practitioner, that sort of thing. And also
17 to divide up the patients so that one clinic or one
18 provider doesn't get too many patients to manage.

19 This will be contractor supported.

20 As far as we know, nobody else has a
21 particular questionnaire that will do all this. A
22 lot of people use health risk assessments that will
23 provide them the preventive services needs, but they
24 really don't provide the rest of the things.

1 If we can get this, we think it will be
2 valuable not only to Region 6 and 4, but probably to
3 all the other medical regions in the Department of
4 Defense.

5 Next slide.

6 Another thing we're involved in is to
7 develop an ambulatory encounter tracking form for
8 the basic training clinics at Wilford Hall. They
9 have about 20 providers and they see about 40,000
10 basic trainees on an annual basis, but they really
11 have no tracking system to monitor what the, you
12 know, the current trends and injuries or illness or
13 that sort of thing and they would like to do that.

14 We're going to use the Navy Smart System,
15 which is a computerized tracking system. We'll
16 implement that at the basic training clinics and
17 follow that, modified as needed, and hopefully
18 provide them the daily, monthly and yearly data on
19 what the health problems and injury problems are in
20 the basic trainees at Lackland.

21 Another thing that the basic training
22 commander has come to us, is that he would like to
23 modify the current physical fitness program that the
24 basic trainees go at Lackland.

1 Right now they've been doing the same
2 physical fitness program for the trainees they've
3 been doing for about 25 years and what they do is a
4 lock-step formation where everybody gets in a flight
5 organization and they run in step at the same pace
6 around and round the cement track for however long
7 they run.

8 The problem with that is everybody's in
9 lock-step, so the pace is determined, of course, by
10 the slowest runner in the flight. So obviously, the
11 slowest runner is not getting improvement very much,
12 and the rest of the people in the flight are
13 probably becoming de-conditioned throughout the
14 seven weeks of basic training.

15 It's probably not a good way to do physical
16 training for the basic trainees. You don't really
17 improve their physical training, so what they would
18 like to do is to modify it, but they want to follow
19 the modifications and make sure that the
20 modifications work.

21 Make sure it does improve the fitness of
22 the basic trainees, make sure it does not increase
23 the injury or illness in the basic trainees and to
24 make sure that we also get the basic trainees to

1 follow up throughout their career and maintain their
2 fitness level by teaching them what fitness is about
3 during basic training.

4 And so we're working on that. What they'll
5 do is they'll have various flights, some of them
6 will maintain the old system, some are going to a
7 modified system where they actually pre-test the
8 individuals. They'll assign them to a fit level,
9 very unfit, fit or very fit and then they will
10 tailor the fitness training of the trainees
11 according to their fitness levels and then they post
12 test them after the fitness -- excuse me, after
13 basic training and figure out if they improved,
14 stayed the same or got worse.

15 As Colonel Parkinson mentioned this
16 morning, we're going to have to put prevention into
17 practice in the Air Force and what we're going to do
18 is we're going to have a technical conference for
19 October, '94. There'll be a planning meeting in
20 August.

21 We'll try to get representatives and
22 experts in preventive service and also some experts
23 who have actually done this in their organizations
24 like Group Health and that sort of thing. And we'll

1 get them together and figure out what the best way
2 to proceed is.

3 How they can overcome the barriers that the
4 services have in getting providers to do this,
5 provider education, patient education, what's the
6 best way to provide the access and what's the best
7 way to actually implement this program.

8 I'm sure most of you have heard, at least
9 in the media, that the Department of Energy came up
10 with some very questionable studies they did in the
11 1950s, where they exposed people to radiation
12 without informed consent and probably did damage to
13 the individuals.

14 Since the DOE had done that, the Department
15 of Defense was very interested in making sure they
16 had not committed similar sins in the 1950s and
17 1960s, so they requested that the -- the Air Force
18 Surgeon General requested that we review all the Air
19 Force research involving radiation that possibly
20 involved human subjects.

21 And so we reviewed all the computer data
22 bases, the Defense Technical Information Center
23 historical records. We actually went out and
24 interviewed the people that did the research

1 throughout Armstrong Laboratory's history and the
2 predecessor laboratory's history and the Air Force.

3 And reviewed all the AFEB histories,
4 because we figured we could find some valuable
5 information in that, and reviewed 40 years of
6 research in the Air Force in three months and,
7 fortunately, we found no smoking guns.

8 There was no adverse effects or no
9 questionable research activities that we found.
10 There was a major undertaking to review all that
11 research in three months.

12 We did do an infant lead screening program,
13 evaluation and since, on the next slide, since
14 Captain Robbins is going to cover that in detail in
15 the next hour, I just want to skip over that one.

16 We also were requested to do an evaluation
17 of prostate specific antigen testing in the Air
18 Force. We had noticed that PSA testing increased
19 358 percent in a two year period at the Epidemiology
20 Division Laboratory alone and it probably increased
21 that much or more in other Air Force laboratories
22 that did PSA testing.

23 We did an evaluation and found out in 1993
24 we did 54,000 tests at a cost of about \$500,000.

1 When we evaluated those, a little over 8,000 were
2 positive, which meant that they would require follow
3 up, repeat testing or follow up medical evaluations,
4 biopsies, that sort of thing. That's an awful lot
5 of patients getting followed up in the Air Force.

6 We also found out that 6,000 tests were
7 ordered on patients below the age of 50 and over
8 5,000 were ordered on patients above the age of 75,
9 which means that at least ten percent of the tests
10 were inappropriate and so inappropriate testing cost
11 the Air Force on an annual basis about \$54,000.

12 What OPHSA recommended was that the Surgeon
13 General develop clear guidelines to the use of its
14 experts in urology and to provide providers
15 throughout the Air Force with clear guidelines on
16 what kind of -- the people they should be doing PSA
17 testing on and what they should do when they do PSA
18 testing and what appropriate follow up they should
19 do on PSA testing.

20 We think this will eliminate some of the
21 inappropriate use of PSA testing and save the Air
22 Force at least \$50,000 annually in laboratory costs.

23 We're getting together two technical
24 advisory boards, really just to tell us where we

1 need to go in various subjects. The two big ones
2 that we're going to have right away are managed
3 care, because we can see that there are a lot of
4 data base needs and information needs that the
5 managed care managers are going to need to do their
6 job.

7 What we'd like to do is get them all
8 together in the military to tell us what they think
9 they'll need. We'd like to get some experts of ran
10 managed care programs like Group Health, Kaiser
11 Permanenti and that sort of thing and tell us what
12 they found out they needed and what they wished they
13 had when they started doing the managed care
14 programs.

15 Likewise, on readiness, we'd like to get
16 the Air Force readiness people together to tell us
17 what kind of needs and information and data bases
18 they need, so that we can provide what we can, you
19 know, from OPSHA, either in data bases, linking data
20 bases or so forth.

21 While they can't meet either organization's
22 complete needs, but they can give us an idea of some
23 needs that we can help them meet.

24 One of the things that the line commanders

1 requested we do is that we test groups that were
2 known to be physically fit to see if the Air Force
3 cycle ergometry program would really show that
4 they're fit. This was the Air Force Materiel
5 Command Commander who asked us to do this.

6 What we did was we tested the special
7 operations personnel and we also tested Marine
8 recruits. The special operations at Herbert Field,
9 we tested the Special Tactics Squadron and when we
10 tested that Squadron, we found that a hundred per
11 cent met Air Force category three guidelines for
12 physical fitness and that 82 percent made category
13 four or higher.

14 We did a support squadron, which had a
15 mandatory exercise program, the people had to show
16 up three times a week and had to engage in about an
17 hour of physical fitness activities. The Commander
18 kind of got out there and went through it with them.
19

20 We found out that 92 percent of them passed
21 CAT 3 and 48 percent went CAT 4 and higher and this
22 was early into the mandatory exercise program.
23 We're going to go back in about a year and see if it
24 hasn't improved, because we think after they've done

1 the program for about a year, it will go
2 significantly, probably approaching this.

3 We also tested one support squadron which
4 had no program and very little interest in the
5 program to see what they were doing and found out
6 that 21 percent of their personnel failed to meet
7 Air Force standards and only 22 percent were CAT 4
8 or higher.

9 So it does make a difference if you're an
10 operational squadron where it's used to being
11 physically fit, if your one where your commander has
12 a lot of emphasis on physical fitness and institutes
13 a mandatory program or whether you're unfortunately
14 like a lot of Air Force organizations that really
15 aren't with a program yet and you're not too
16 interested in it.

17 We also went to the Marines, the Marine
18 Corps Recruit Depot at Camp Pendleton and we tested
19 some Marine recruits in week nine of basic training.

20 All the Marine recruits met CAT 3
21 standards.

22 Only 3 percent scored in CAT 3. None
23 scored in CAT 2 or CAT 1. All scored at least CAT 3
24 and 96 percent scored in CAT 4 or higher, which told

1 us that if you actually do the cycle ergometry
2 program in groups that you know to be fair, at least
3 in young, fit individuals, it does seem to show that
4 they are fit.

5 It may not give you the exact VO2 max that
6 that individual has. You'd have to compare that
7 with the maximum treadmill -- Doctor Parkinson's
8 going to get into that later today, but it does show
9 you that they do score in the proper categories.

10 Let me run through the last two real
11 quickly. Preventive services benefits for tri-care
12 were asked to come up with a benefit package to put
13 into the managed care program for tri-care in Region
14 6.

15 We did recommend that age and gender
16 specific preventive services be a basic benefit, be
17 enrolled in the basic benefit package, so that
18 preventive services got an entry into the benefit
19 package because, as you know of, in CHAMPUS and a
20 lot of other things, they're not part of the
21 program.

22 We did recommend they become a basic part
23 of the basic benefit program. We recommended that
24 HRA be included in the enrollment process and we

1 recommended that education programs for providers
2 and patients be developed to tell them what they
3 needed and how to provide preventive services to
4 their patients.

5 And we recommend that you integrate this
6 with the PPIP efforts and we also would like to
7 recommend to Region 6 that when they do this, they
8 become a possible model for other regions so that we
9 could get into the other regions eventually, so that
10 all military beneficiaries had preventive services
11 as part of their basic benefit package.

12 And we're just also developing a uniform
13 table of allowances for an epidemiology team that
14 would go and deploy in situations like Somalia or
15 Desert Storm or something that would actually go and
16 deploy. We'd like to know what kind of members of
17 the team, you know, how many preventive medicine
18 physicians, entomologists, that sort of thing you'd
19 need and also what kind of equipment they would do.

20 Some of our -- those future projects we'd
21 like to define and implement a centralized medical
22 research data base. We need to determine the
23 preventive services needs, the availability to those
24 services and efficiencies in the San Antonio area

1 and then eventually expand that to Region 6 and then
2 throughout the Air Force.

3 Develop preventive services policy
4 guidelines for the Surgeon generals so they can put
5 those out and implement those. We'd like to
6 evaluate health promotion programs for
7 effectiveness. As I mentioned earlier, we really
8 need to do that.

9 I'd like to provide health services, health
10 needs, not just preventive services needs, but the
11 entire health needs for Region 6 and we are going to
12 provide some analysis to support the medical support
13 agency, which is our computer people, medical
14 computer systems people in the Air Force.

15 They're losing a lot of people in the
16 cutbacks and we'd like to provide them some analysis
17 support and I think that's my last slide.

18 I know I kind of ran through this real
19 quickly because we're kind of behind time, but we're
20 very early in the process of implementing in this
21 organization, but we do have a lot of projects we're
22 involved in. We have a lot of things we'd like to
23 do and we're trying to do it as fast as we can.

24 We do have a budget. Not very many people,

1 but we do have a budget and we are getting started
2 and we can probably provide an update once we're
3 fully implemented and fully involved.

4 And I'll answer any questions you have
5 right now.

6 VOICE: I commend you on your very detailed
7 outline for prevention. I think there are a number
8 of things that could be commented upon. The symptom
9 driven health care prevention often is better
10 sometimes than doing a routine PSA, as you found
11 out, that this can be really misguided, so to speak,
12 and there are a lot of guidelines out. This new
13 journal covered a lot of prevention areas in the
14 last few months.

15 PSA, for instance. Their guidelines for
16 exercise and other things of this nature and I think
17 is bringing in a very nice structure. I was
18 interested in your bringing in outside physicians.

19 I think a component of health
20 professionals, physicians from academic centers, as
21 well as maybe in the private area to benefit each
22 group, yours and those that are out there looking at
23 this. I think this is a very good model.

24 COLONEL WRIGHT: Yeah, we'd like to get the

1 experts from all different fields, you know, that
2 are specific to the project that we're working in.

3 VOICE: Yes. And the things are timed well
4 with Mike Parkinson's exercise of test evaluation,
5 and he'll talk about it, I think is very good.

6 COMMANDER UNGS: On this Coast Guard, what
7 type of -- regarding active duty populations, do you
8 have any thoughts on how you're going to evaluate
9 outcome measures for prevention services?

10 For example, is it reduction in number of
11 personnel discharged for disabilities or fitness for
12 duty days or mortality? I mean have you given it
13 any thought specifically?

14 COLONEL WRIGHT: Well, we haven't
15 specifically developing protocols for those yet, but
16 we are thinking about them. We do have some data
17 bases at Randolph Air Force Base that will give us
18 information of what people are medically boarded for
19 and what their disabilities were when they were
20 medically boarded, so we can get rates and that sort
21 of thing.

22 But health outcomes measures is a big --
23 it's going to be a big project and, right now, we
24 really don't have the basic data bases to get the

1 information to even start doing that.

2 So that's what we're going to do to start
3 with, is get the data bases in place or at least try
4 to get the data bases in place so that we can get
5 the baseline information and monitor that and then
6 tease out of that the information on the health
7 backgrounds, both the medical data bases and
8 demographic data bases.

9 COMMANDER UNGS: One thing that I
10 observed and I'm sure it's similar for other health
11 agencies is that the health dollar competes against
12 other dollars, fuel, planes, et cetera.

13 And one question that's brought to me as a
14 health person is that is it not cheaper or better
15 for the organization to essentially discharge
16 someone as unsuitable, rather than to spend the
17 money for prevention service so that the kind of
18 healthier life, at some point -- from an
19 organizational standpoint. Can you give me a
20 thought on that?

21 COLONEL WRIGHT: Yeah, I have -- excuse me,
22 sir, General Hoffman has his hand up. Well, I think
23 I've answered that one. General.

24 (Laughter.)

1 GENERAL HOFFMAN: In the Department of
2 Defense, at least at the operating level, the peace
3 time health dollars are completely separate from the
4 guns and ammunition and fuel dollars, so at the base
5 level, at the community level, the garrison
6 commander or wing commander does not have to make
7 decisions about whether to buy medicine or fly the
8 jets. We're thankful for that.

9 I think that, you know, what we all
10 believe, and I think the data's there to support it
11 to a certain extent, is that it costs less to keep
12 people healthy than it does to treat them when they
13 get sick.

14 The problem in that statement is that
15 there's a certain amount of data and a certain
16 amount of intuitive belief and the other problem is,
17 is that there's sort of some cash flow problems. It
18 may take a while to invest in prevention before we
19 see a reduction in the number of people getting sick
20 and the resource consumption that goes along with
21 that.

22 But I can tell you, I think, from the Air
23 Force's standpoint and I think from the other two
24 Surgeon Generals' standpoint, it is obvious that the

1 time has come, in fact, it's probably gone by, but
2 the time has come that we now have to -- we cannot
3 afford to keep putting money in to buy medicine and
4 treating illness.

5 We are at some point, and we think that
6 point is now, at a point where we're just going to
7 consume all the money in the Defense Department if
8 we keep that up. Therefore, we in fact are going to
9 invest in health, invest in wellness and invest in
10 the future, with the idea that the return on that
11 investment will come in the future.

12 Now, we're going to invest both in broad
13 sort of encouraging ways of lose weight, exercise,
14 don't smoke, eat right, sleep a lot, get along with
15 -- don't beat your wife, you know, all those sorts
16 of exhortation things.

17 But the other thing that we're going to do
18 is we're going to use our data bases to focus on
19 what are our most common conditions for which people
20 seek care? What are the most expensive conditions
21 for which people seek care is the care they're
22 getting, the best care for the amount of dollars.

23 So we hope to use the information to focus
24 not only on prevention, but also on smarter resource

1 utilization at the present time in order to help
2 sort of fund the future.

3 COLONEL WRIGHT: And we'd like to monitor
4 the interventions we do to make sure they're
5 effective and saving money and doing what they're
6 supposed to do also. We haven't done that very good
7 in the past.

8 VOICE: Just a response back to your
9 suggestion about discharging people who have been
10 trying to maintain health. I think it costs a lot
11 more to try to replace a trained, experienced
12 person, than it does to keep them fit and healthy.
13 I clearly agree with Dr. Hoffman that prevention is
14 the way to go on this.

15 COLONEL WRIGHT: Certainly with pilots who
16 cost several million dollars to get fully trained,
17 that's very true.

18 DR. KULLER: One more question.

19 DR. BROOME: Just to get an idea of where
20 you may be going with some of the data bases, are
21 you now or are you planning to follow through with
22 the PSA evaluation to identify the predicted value
23 of a positive test in your population, the predicted
24 value of a negative test, the ultimate health

1 outcomes?

2 COLONEL WRIGHT: Well, we probably will,
3 but we haven't been tasked to do that yet, so we're,
4 to be honest with you, have so many projects going
5 right now, we don't have the resources to do it
6 until we're officially asked for it.

7 So we've recommended that be done, but
8 we're not in the process of doing it right this
9 minute, no.

10 GENERAL HOFFMAN: The organization was
11 brought a specific question to which they gave a
12 specific answer. That's one of the roles of the
13 organization.

14 If in the analysis of where the money is
15 going and what the diagnoses are that are consuming
16 the resource of either the people or the dollars, if
17 somehow something associated with PSA is floated to
18 the top of that list, then that would be addressed
19 in a systematic way.

20 So the organization is really sort of -- it
21 is going to address things systematically, but it's
22 also going to be a resource for people with specific
23 questions at specific times. In this particular
24 case, the PSA question was a single point question

1 for which they provided an answer.

2 COLONEL WRIGHT: We did find out at the
3 investigation that one of the reasons are the
4 inappropriate testing is done is that the patient
5 simply won't leave the office until the doctor
6 orders the test.

7 So one of the recommendations is devise a
8 fact sheet for patients to give them to read to come
9 back and maybe educate them a little bit that they
10 really don't need the test. It can be more harm to
11 them then value.

12 GENERAL HOFFMAN: And assertiveness
13 training for the doctors.

14 COLONEL WRIGHT: Yeah, that's always good.

15 (Laughter.)

16 COLONEL WRIGHT: Well we didn't recommend
17 that, but that's true. Okay? Break time?

18 DR. KULLER: We'll have a break now for
19 about fifteen minutes

20 (Whereupon, at 3:00 o'clock p.m., a recess
21 was taken until 3:20 o'clock p.m.)

22 LIEUTENANT COLONEL PARKINSON: Thank you,
23 Colonel Peterson. Just a couple of personal
24 observations. It's a real pleasure to follow both

1 Commander Gray and Colonel Wright.

2 Greg and I trained together during
3 residency and it's nice to see that he continues to
4 take what I consider to be small, non controversial
5 subjects and make sense out of them, so I want to
6 thank him for that.

7 Also, Colonel Wright, who many of you know
8 served as my predecessor for nearly six years as the
9 Air Force Preventive Medicine Consultant. It's a
10 personal pleasure to follow him and I wanted to let
11 Jim know that he's still getting phone calls.

12 I've not had the heart to tell these people
13 that he's left and I've not returned them, so Jim,
14 if you'd stop by the office --

15 (Laughter.)

16 LIEUTENANT COLONEL PARKINSON: -- there's
17 a whole stack of people who'd like to talk to you.

18 Finally, I can assure you that nothing
19 related to fitness testing or cycle ergometry has
20 anything to do with the Gulf or mogiditia for that
21 matter, so let's take a breather for a few minutes.

22 Many of you know the Air Force introduced a
23 radical change in its fitness testing program,
24 moving from the mile and a half run to the use of

1 sub maximal cycle ergometry.

2 At the outset, I want to thank Dr. Jerry
3 Fletcher, a member of the Armed Forces Epidemiology
4 Board, for his ongoing consultation in support of
5 this program to the Surgeon General.

6 I think the collaboration that we had with
7 him over the past seven, eight months or almost a
8 year now represents the type of ongoing consultation
9 that I consider valuable as one of the consultants
10 in which we would hope to foster with each of you
11 over the long run in your respective areas of
12 expertise.

13 So today I'd like to talk to you about two
14 things that have been new developments in the last
15 four months which both have been major in the
16 program. The first is a validation study that was
17 conducted by the University of Florida Center for
18 Exercise Science by Dr. Michael Pollack.

19 And the second is a two day Air Force
20 fitness program summit which was recently convened
21 in San Antonio and which Dr. Fletcher graciously
22 attended and contributed to. So if we can have the
23 first slide, please. I'll try to use a laser beam
24 here.

1 Dr. Pollack was gracious enough to allow me
2 to use his slides for this presentation. For many
3 of you who may not know, Dr. Michael Pollack is a
4 world renowned exercise physiologist who runs the
5 Center for Exercise Science in Gainesville and has
6 published numerous textbooks and articles on
7 exercise testing and fitness generally.

8 Next.

9 Briefly, there have been a wide variety of
10 ways to assess fitness, cardio respiratory
11 endurance, strength and flexibility. In 1968, the
12 Air Force went to the mile and a half run, which was
13 pretty much a maximal stress field test.

14 Running a certain mile and a half in X
15 number of minutes correlates with a certain VO2 max
16 as measured on a treadmill. And the Air Force had
17 been using that for many, many years. We basically
18 discovered briefly, however, that the program was
19 not being implemented well in the field.

20 Furthermore, it was certainly not
21 motivating people to enhance fitness on an ongoing
22 basis. It wasn't quantitative in nature, it was,
23 you know, a dichotomous yes/no, you pass. And of
24 real concern was the number of injuries, an

1 unsupervised maximal stress test that was conducted
2 once a year in an otherwise sedentary population.

3 We estimated that two to four deaths a year
4 in the Air Force population were resulting as a
5 result of this test and, indeed, further studies
6 that were conducted more systematically by the Navy,
7 looking back since about 1989, had demonstrated
8 similar numbers in their population, using a similar
9 maximal stress test.

10 So we just asked ourselves, isn't there a
11 better way to do it and indeed, we felt there was.
12 And that was sub maximal cycle ergometry, which was
13 basically developed approximately 50 years ago now
14 by Astrin Reiming in Sweden, and has been used for a
15 number of years by numerous organizations, including
16 the YMCA since 1973, to estimate maximal aerobic
17 capacity or VO2 max, which is an estimate of cardio
18 respiratory endurance.

19 The Chief of Staff of the Air Force,
20 approximately two years ago now, endorsed this
21 method of assessing fitness and motivating Air Force
22 members to improve their cardio respiratory
23 endurance.

24 Next slide.

1 What we wanted to do was take our existing
2 protocol which essentially is an Astrin Reiming
3 protocol with one or two variable changes developed
4 by researchers at Brooks Air Force Base and have it
5 looked at by an outside agency, an outside
6 authority, Dr. Michael Pollack, to determine how
7 well this slight variation of an already 50 year old
8 algorithm was truly approximating VO2 max as
9 measured on treadmills.

10 Was it a valid test, a valid estimate of
11 VO2 max on treadmill for our age population, 18 to
12 54? Did it correspond to people who exercise? Did
13 people who exercise more score better than people
14 who didn't? Did the training mode -- if you were a
15 cyclist, did that matter more than if you were a
16 jogger or a weight lifter?

17 And we also wanted to determine some of the
18 specific questions, whether or not testing at
19 certain work loads versus others would increase the
20 predictability of the test.

21 Next.

22 We wanted to see whether or not our product
23 compared as well, better or worse than the existing
24 YMCA protocol, which uses the same principle, but a

1 slightly different algorithm . We wanted to
2 determine what proportion of invalid tests, for
3 whatever reason, invalid is probably the wrong word,
4 inadequate test.

5 In other words, in which proportion of
6 individuals was the test failing the individual,
7 that is they actually were fit or their actual VO2
8 max standard was considerably higher than what we
9 were predicting on the bicycle test.

10 Could we add other variables to improve the
11 predictability of this equation, to increase the
12 correlation coefficient or the mean difference
13 between what we were measuring on the bike versus
14 what we were measuring on the treadmill.

15 And programmatically, what proportion of
16 people were we potentially misclassifying, treating
17 it as a medical screening value. In other words,
18 what's the sensitivity, specificity and positive
19 predicted value of this Public Health screening
20 test?

21 Next.

22 I want to share with you just a few of the
23 slides and they're rather busy, but let's try to go
24 through them. Very quickly, the gold standard for

1 all of this, of course, is the maximal generally
2 Bruce protocol treadmill test with direct
3 measurement of VO2 max.

4 Cycle maximum test, in other words, using
5 the cycle ergometry but going to full exhaustion
6 similar to the Bruce protocol, generally has a
7 correlation of .95 to .98 with the gold standard and
8 a small standard error. They're both maximal stress
9 tests.

10 When we start moving down into -- let's
11 skip that one -- down to field testing, away from
12 the equipment in the maximal stress test, we find
13 the correlation coefficients fall off slightly and
14 the standard errors increase a little bit.

15 Likewise, sub-maximal tests, which instead
16 of going to a hundred percent or 95 percent of the
17 person's estimated maximal predicted heart rate,
18 likewise you lose a little bit, but not much. The
19 correlation coefficient is .7 to .85 and the
20 standard error is just about the same.

21 In addition, however, remember we have the
22 motivational factor and we have the safety factor.
23 There's a huge different in safety factors and in
24 motivational factors, based on our experience in the

1 Air Force between those last two bullets.

2 Next.

3 The study population for this, there was
4 numerous studies that were done on the population.
5 I want to describe 134 individuals, 67 males, 67
6 females of low, medium and high fitness categories.

7 Okay?

8 On the right hand side represents the
9 number of individuals we were trying to recruit in
10 each cell. The left hand side represents in yellow
11 where we basically met or exceeded those numbers; in
12 the red where we did not meet them. That should
13 probably be a red, for example.

14 But what we found was that at least in
15 Florida, it's hard to find some young low fit males.
16 I guess that's why they're in Florida. Likewise,
17 we had a little bit of problem in the young low fit
18 females, at least around Gainesville.

19 But for the other categories, we pretty
20 much found a mix, as we wanted to, of low, medium
21 and high fitness categories, males and females, and
22 ages, which is the distribution of ages in the Air
23 Force population.

24 Next.

1 The methods basically were this. They get
2 the baseline sub-maximal cycle ergometry test,
3 pulmonary functions, looking at pulmonary function
4 tests. Then they go on to get the gold standard
5 test. Okay? The treadmill max, Bruce protocol and
6 then a series of repeat tests for looking at test-
7 retest reliability, as well as for slight variations
8 in the algorithm that would improve predictability.

9 Additionally, Dr. Pollack's looking at
10 other variables that we might add to the equation,
11 percent fat, fat free body mass, things like that.

12 Next.

13 Continuing, you look at different
14 variations and what we do with the work loads.
15 That's kilipons, basically work load equivalent.
16 We're looking at a maximal cycle test. Does the
17 sub-maximal test predict the maximal cycle test or
18 the maximal treadmill test better?

19 And finally, how does it compare against
20 the other widely used standard out there, the YMCA
21 sub-maximal test?

22 Next.

23 Briefly, the results. I'll spend a minute
24 on this. Males, females, and we're looking at the

1 first sub-maximal cycle test. The second, third
2 sub-maximal test compared to the gold standard, the
3 treadmill test and let's just concentrate on this
4 column.

5 For men what we found as a population, that
6 the sub-maximal cycle ergometry underestimated on
7 average by about two milligrams per kilogram per
8 minute of VO2 max. The correlation coefficient was
9 about .85 with the treadmill. Standard error of
10 about 5 to 7, 6.7 right here.

11 Among the females it was just the converse.
12 It overestimated females by about the same amount,
13 2.2. Correlation coefficient about the same,
14 slightly different, slightly lower standard error.
15 But again, the numbers upon which this is
16 calculated, men and women have different VO2 max's
17 for the same age so you'd expect it to be smaller as
18 well.

19 Next.

20 If we look at for men and women versus the
21 YMCA test, okay, what we basically found is that
22 compared to the YMCA, compare your baseline versus
23 the YMCA, we basically see that for men, basically
24 the mean difference between the Air Force test

1 versus the YMCA test, that the Air Force test was
2 closer to the mark and that the correlation was
3 considerably better, .86 versus .63.

4 Among women, it appeared to be equivalent
5 or perhaps slightly a little bit better, the YMCA.
6 The numbers were a little different, but a marked
7 difference in the Air Force, particularly among the
8 men.

9 Next.

10 VOICE: What's the normal range that you're
11 plus?

12 LIEUTENANT COLONEL PARKINSON: Okay, I
13 didn't have that slide in here, but basically -- I'd
14 have to dig it out quick to see what the mean was in
15 this population, but basically for men we're talking
16 about in the orders of 38, 40 or so. I think for
17 women it's on the order of about high 20s, low 30s,
18 that type of thing.

19 So the percent, when they look at the
20 percent standard error, that's basically how you can
21 calculate it. The percent standard error in most of
22 these is about ten to fifteen percent for your
23 standard error.

24 But also we wanted to look at subgroups and

1 it's very important. As many of you know, when you
2 look across at a correlation coefficient across an
3 entire population, that what you really do is you
4 underestimate the variability at the extremes.

5 And so it's very important for this test,
6 particularly from a policy standpoint, to see what
7 we're doing with the low fit and the high fit
8 individuals. And in the low fit individuals, okay,
9 those are people that we're calling Categories 1, 2
10 and 3 and I'll get to that in a minute.

11 What we find is that the mean difference,
12 that for men, it underestimated by as much as 5 to 6
13 the miles per K per minute and the correlation
14 coefficient dropped, whereas in the high fit it
15 predicted quite well.

16 Following slide.

17 And following along -- next slide -- and
18 just as we saw before with the females, the same
19 converse difference was seen among females. That is
20 among the low fit females they predicted relatively
21 well, that is the mean difference was only two off,
22 whereas among the high fit females we were
23 significantly over predicting the high fit females.

24 So to summarize, what we were doing is kind

1 of systematically, but slightly, underestimating VO2
2 max among males and overestimating VO2 max among
3 females. And those effects were greatest among low
4 fit males respectively and high fit females.

5 Next slide.

6 By adding certain other variables and I
7 won't go into all of these, we could increase
8 slightly the correlation coefficient with little or
9 no effect on the standard error of the test.

10 The question became programmatically this
11 is interesting because it's retrospectively done on
12 the population we just studied, but to add these
13 variables at this date without doing another
14 validation test, we would be using an invalid or an
15 invalidated equation prospectively on the Air Force
16 population, so this is an area for future study.

17 Next slide.

18 The other issue is sensitivity and
19 specificity and this is treadmill, the gold
20 standard, two by two table, this is the Air Force
21 sub-maximal cycle ergometry test.

22 And for the purposes of our program, we
23 call Category Level 3 as the cut point for what we
24 administratively consider to be fit or unfit in the

1 Air Force. So of course the true positives and the
2 true negatives were interested in most here.

3 And what we basically find as you do the
4 numbers here, that the sensitivity of the test to
5 detect individuals below Category Level 3, is about
6 75 percent and the specificity of the test to detect
7 those individuals is about 96 percent.

8 Next.

9 Dr. Pollack's summaries, the summary of his
10 findings basically, the sub-maximal cycle ergometry
11 test is a valid test for males and females, ages 19
12 to 54 and a good estimator of VO2 max. As a matter
13 of fact, it's better than the YMCA protocol and more
14 systematically studied and evaluated than the YMCA
15 ever was.

16 It relates with the treadmill VO2 more
17 closely than cycle VO2 max. I did not show you that
18 data, but it is a better correlate of the gold
19 standard than of the sub-gold standard cycle
20 testing. The VO2 max estimator is improved with
21 slight variations of work load settings. The YMCA,
22 it's inadequate for males, it's probably okay for
23 females and it had 28 percent of invalid base tests.

24 Next slide.

1 I'd like to comment on the invalid baseline
2 test. What that means is that basically the work
3 load was turned up too quickly on the individual,
4 such that when they were stressed with that work
5 load on the bike, they exceeded their maximal
6 allowable heart rate. They went above the 75 to 80
7 percent that is allowable of their maximal heart
8 rate for the purposes of a sub-maximal test.

9 So when you retested those individuals, you
10 did fine, but initially when they tested, they
11 busted their maximal heart rate. The concern that
12 we have programmatically is in the field, in the
13 hands of less experienced testers, that those people
14 are being told, quote, you failed the test, you're
15 not fit.

16 It's a logistical problem, it's an
17 educational problem, but it's very significant in
18 terms of program credibility and particularly
19 program enhancement.

20 Can we move to the overheads now?

21 Well, with that study in hand, we basically
22 convened -- there's a title slide, I believe, on
23 that. We convened for two days a half assed
24 backwards Air Force fitness program seminar.

1 (Laughter.)

2 LIEUTENANT COLONEL PARKINSON: It really
3 wasn't backwards, it was a forward looking project.

4 But what we did is we basically had a lot of
5 information. We needed to pull together people from
6 both inside and outside the Air Force to say here's
7 where we're at 18 months, two years into this
8 program. What can we do to make it state of the
9 art, what can we do to work out the bumps and
10 glitches and respond scientifically to the study
11 that we had just funded, to look at how the protocol
12 did?

13 And to that end -- next slide -- we invited
14 a wide variety of people from the Air Force,
15 including people who developed the test. The first
16 two were just bureaucratic functionaries, don't pay
17 attention to them. Secondly, though, was partners
18 in Air Force Services.

19 Air Force Services is that aspect of the
20 Air Force that runs our Health and Wellness Centers.

21 There has been a decision that we are going to move
22 to centralized ergometry testing. That is, have a
23 central focus, a central place on base that is run,
24 staffed, equipped and appropriately trained for

1 individuals to do quality cycle ergometry
2 evaluations.

3 And therefore, when you see SV, our
4 partners in the deployment of this program are the
5 services community, who are very interested in this
6 program. Armstrong Lab, of course, the folks who
7 developed and fine tuned the test, people from the
8 Pentagon involved in services, Dr. Pollack from the
9 University of Florida, Dr. Fletcher, who also
10 serves, as I mentioned, on the American Heart
11 Association Committee on Exercise and their
12 standards testing, representatives as well from two
13 of our major commands that are very vested in this
14 program, AFMC and Air Mobility Command.

15 Next.

16 And what we did is we looked under every
17 single rock to find every snake that we possibly
18 could with this program. This is an outline -- I'm
19 not going to cover all of these, but for two days we
20 defined challenges and problems in each one of these
21 areas and how could we improve the administration,
22 the understanding, the science of the program, as we
23 go to press with the instruction that will institute
24 this Air Force-wide.

1 Next.

2 I already talked before about the
3 University of Florida's cycle ergometry validation
4 study.

5 Next.

6 And their recommendations. That to modify
7 the regression equation, to cross validate new
8 equations before fielding, don't just throw it out
9 there with new little quirks in the computer
10 program, and it changes somehow to decrease the
11 invalid tests.

12 Longer time at each work load can be
13 accommodated really only by changing the software
14 and a warm up period. What we were finding was if
15 the test started right away with individuals having
16 a heart rate monitor to work load, that many of them
17 had elevated heart rates just through the anxiety of
18 getting on the bike.

19 So the recommendation was to include a two
20 minute mandatory warm up phase at a very low level
21 of work, to accommodate some of the anxiety that
22 goes along with the testing.

23 Next.

24 The other question -- we had received

1 numerous questions. Well, gee, I read somewhere
2 that, you know, if I basically -- Mexican Americans
3 have a different relationship in terms of their
4 exercise tolerance or that smoking vastly affects
5 your VO2 max. Medications, anxiety factors, and we
6 went bullet by bullet over these with Dr. Fletcher
7 and the panel.

8 And what we basically found is that yes,
9 well some of these factors may have small effects on
10 sub-maximal heart rate values. That the biggest
11 single predictor by far and away is ones fitness
12 level and ability to perform cardio respiratory
13 endurance type work.

14 And that therefore, we are developing a
15 consensus statement on each one of these, reflecting
16 the state of the science, state of the art as it is
17 in 1994 and committing ourselves to doing some
18 ongoing research where it appears to be indicated
19 from large scale studies that have really not been
20 done yet. And two of those areas are probably in
21 the area of smoking and perhaps in the area of race,
22 as well.

23 Next.

24 The testing protocol and algorithm

1 decreased the number of invalid tests and improved
2 the prediction. We basically accepted Dr. Pollack's
3 findings. We're going to look at prolonged work
4 load time periods in the next iteration of our
5 validation study. We're incorporating the warm up
6 period now, immediately in directions to the field.

7 Next.

8 Standards and scoring. It was decided
9 early on that we would basically take the VO2 max
10 scores and put them into categories. And
11 unfortunately, what has happened is we had more
12 categories than we had room for the standard error
13 of the test. And it turns out that the categories
14 were narrower or equal to the standard error.

15 And what that did is it made us measure the
16 precision of millimeters with a yard stick, such
17 that an individual could quite easily test a Level 4
18 one time and a Level 3 another time. And, as a
19 matter of fact, it was kind of likely, given the day
20 to day variation.

21 As I said to many people that I work with,
22 it's a little bit like saying you have high normal
23 blood pressure instead of saying your normal is --
24 your blood pressure number is 136 over 82. We've

1 got to get back to giving people their absolutely
2 VO2 max scores and explain to them where that puts
3 them in the spectrum of people in the Air Force and
4 where it puts them in the categorization.

5 So what we wanted to do was change from six
6 categories to four in five year rather than ten year
7 age groupings. There's nothing automatically that
8 says that there's a precipitous drop in your VO2 max
9 from the age of 29 to 30. It's a gradual process
10 that's physiologically true. Why shouldn't we
11 reflect it that way in our tables? So we're going
12 to five year rather than ten year age groupings.

13 Next.

14 To give you an example, under current and
15 revised, I don't need to go through this, but you
16 can just see that if individuals in one standard
17 error of their true value, under the current method
18 for man, can be anywhere from a Category 2 to
19 Category 4, whereas under revised broader
20 categories, this is not rocket scientist, they'll
21 still be within Category 3.

22 What people take away from this program, if
23 they tested Category 3 once and in Category 4 the
24 second time and they haven't changed their exercise

1 regimen is this program is bunk. But in reality,
2 what we've done is we've created a false sense of
3 precision by too many categories. So by going to
4 broader categories, we'll be able to change that
5 mis-perception.

6 Next.

7 Data analysis and management. High level
8 interest, line interest, Chief-of-Staff interest on
9 how the Air Force fitness levels are doing. We need
10 to upgrade our current software through ongoing
11 contracts that we have with the Armstrong Lab.
12 We're going to probably out source, we're not going
13 to do this.

14 We eventually want to get to the point
15 where we have an automated system, that we work with
16 a private contractor just as we do competitive bids
17 with everything else that we do in the Air Force,
18 and what we want to do is synchronize our software
19 changes with reporting periods for ease of
20 transition at the base level.

21 This could become an onerous task if you've
22 got one set of software that says one set of
23 categories, but yet the Military Public Health
24 Officer or our fitness coordinators have got to go

1 over to another table and look up what it really is
2 under the revised categories and then report it out
3 manually for 430,000 active duty troops.

4 So we need to make sure that we go lock-
5 stepped to make it easy for our people at base level
6 to administer this program.

7 Next.

8 To that end, what we're going to do is
9 we're providing better questions, better software
10 support. I'm stuck on screen Number 3. How can I
11 get off that or this person has a question about,
12 you know, why does the work load go from X to Y.

13 We have a contract developed, people to do
14 that, along with folks from Armstrong Laboratory and
15 Colonel Wright's shop. We're developing an RFP for
16 the next iteration of improvement in the algorithm,
17 possibly looking at logarithmic transformation of
18 the equation, which is probably the easiest thing we
19 can do to increase the predictability of that
20 particular equation.

21 And I already mentioned the blanket
22 purchase agreement long term. We immediately --
23 next slide -- we briefed General Sloan on this about
24 two weeks ago. He authorized \$135,000 for the

1 immediate upgrade of the software, which we will put
2 on the street beginning in January, '95.

3 At that time we will have incorporated the
4 warm up period. We will have incorporated the new
5 way of reporting scores, so that individuals know
6 their number. We can even use the same slogan that
7 the NCEP used for cholesterol, know your number.

8 And during that time period, we will also
9 start a massive educational campaign revising all of
10 our materials, doing interviews with folks such from
11 Air Force Times and things like that.

12 Next slide.

13 Training and education, we've already
14 revised our basic course. We want to basically go
15 through standard certification methods, the American
16 College of Sports Medicine. Colonel Jim Dale, our
17 Chief of Health Promotion, has been working closely
18 with people from services to get people who will be
19 working with and running those Health and Wellness
20 Centers, to have state of the art tickets so that
21 they are really up to speed on what a Health and
22 Wellness Center should do and how we do fitness
23 testing appropriately.

24 A resource manual is going to be developed

1 and completely revised with chapters in it for the
2 Commander, for the medical officer who's the medical
3 consultant. If any of you are like me, in medical
4 school I didn't learn anything about VO2 max. I
5 didn't even know what it was and yet in many of our
6 bases, it's the physician, the family doctor, the
7 flight surgeon, the internist who's the tie breaker.

8 And we need to do a better job of informing
9 them about the tests, how it works and what they
10 should know about it. We need to develop more
11 people at the MAJCOM levels who become resources
12 within their own commands.

13 We have many people in the aerospace
14 physiology community who are physiologists by
15 training who are interested in this program. We
16 should be able to use their expertise and automate
17 the system. Right now, it's a very tester dependent
18 system. We want to make it as much of a black box
19 as possible. We think we can do that and given the
20 right equation, I think we will.

21 Next.

22 Conclusions. Dr. Pollack has said
23 basically the Air Force has the best, most validated
24 protocol for sub-maximal cycle ergometry testing in

1 existence. It's much better than the YMCA for our
2 population and it's been more thoroughly studied
3 than any one around.

4 There was a brief to General Sloan and
5 General Sloan, with the exception of one or two
6 small items which do not appear in this briefing,
7 endorsed the entire recommendations of the summit
8 meeting. I think he was confident that represented
9 the best minds that we had for two solid days of
10 work to come up with what is a proactive and we feel
11 a very successful program.

12 We need a lot of education and we're going
13 to continue to do that. Part of that education
14 involves a joint letter going out to all of our
15 services people and the Surgeon Generals community
16 that will summarize most of what I've told you here
17 today.

18 So I'll end on that note and I'm not sure
19 where we stand with time, Dr. Kuller, but if you'd
20 like to take questions, I will.

21 DR. KULLER: Are there questions?

22 I have one question which is related to
23 your -- partially to your last two presentations,
24 but maybe again, it confuses me and may be a little

1 bit of an update.

2 A couple of meetings back, maybe two or
3 three meetings back and in some time that I spent
4 with -- Bill Harlan and I spent in Washington, there
5 was a big concern about exercise testing, exercise
6 programs in the military and the problem that they
7 weren't predicting the risk of dropping dead while
8 you were exercising. And this was of some concern
9 in the military because of the high proportion of
10 people dying suddenly from heart disease were doing
11 it during exercise.

12 How does the two program -- your program
13 and the previous discussion relate to the monitoring
14 of the predictability of these tests in terms of
15 potential adverse effects of vigorous exercise,
16 especially when you're talking again about cigarette
17 smoking, overweight individuals, individuals with
18 hypertension, et cetera?

19 LIEUTENANT COLONEL PARKINSON: Well, your
20 later comment is probably most relevant and that is
21 that this program, of course, does not operate in
22 isolation from other health promotion efforts and
23 certainly all of those other programs are ongoing
24 and complimentary to this.

1 I think it's very fair to say that both
2 Congress and GAO have been interested in the whole
3 issue of physical standards, in deployability, in
4 fitness testing and in fitness testing related
5 deaths in the last year.

6 And even as we speak now, the DOD directive
7 on fitness is being drafted yet again, that would
8 basically be the umbrella for all the services'
9 policies. I can tell you from our experience that
10 we have identified deaths associated with the
11 maximal stress run.

12 The Navy has identified those types of
13 deaths more systematically than we have perhaps, but
14 in that general sense, I can tell you that this is
15 probably right. This type of program is going in
16 the right direction for both reasons, both because
17 it's safer and also because it's more quantifiable.

18 So for that reason, we can go back now a
19 year from now or last year and I can show you what
20 proportion of individuals in the Air Force met the
21 standard versus meeting it now.

22 Finally, the purpose of the whole program
23 is participation in a regular aerobic exercise
24 program and for that reason, we found that this

1 program that gives people a marker, it gives them
2 something that they can measure themselves against
3 and prove over time, that that does that.

4 General Hoffman.

5 GENERAL HOFFMAN: The other program before,
6 the running, which is where people die, was a thing
7 where someone would not exercise and smoke,
8 overweight, no exercise and they'd get out there on
9 a hot day and say I can do it, I can do it, and
10 they'd run until they die.

11 The bicycle ride is a sub-maximal test that
12 in fact as soon as your heart rate really starts to
13 accelerate, the test is over, and you cannot sort of
14 go out and gut it out. It really is a reflection of
15 your physical condition when you go to take the
16 test. It's something you can't just get ready for
17 in a day.

18 So it is a better reflection and it is
19 medically, it is much, much, much, much safer than
20 the other tests.

21 DR. FLETCHER: Fletcher. Let me expand a
22 bit on that maybe. The test being done in the Air
23 Force now is really to assess a level condition,
24 it's not to really diagnose disease or to look for

1 things that might predict sudden cardiac death.

2 I think in that setting is the family
3 history, the over weightness, the smoking, other
4 risk factors an individual has who takes this test,
5 but I think the test is safe beyond the shadow of a
6 doubt compared to the knowledge I have of other
7 testing and other ways this was done in the past
8 where we were very concerned that many others have
9 died from this.

10 So I think it's a different type of test,
11 but a very, I think, scientific type thing. The
12 warm up period, I think will help. Many of these
13 individuals are, as I understand their emotion and
14 perhaps their salary and their job, are somewhat
15 confused by this test and they were quite worried
16 about it.

17 A little warm up period of a couple of
18 minutes will have the time for reversing and
19 settling down and perhaps the tester to give some
20 instructions about the test and give a much more
21 scientific, very accurate estimation of the VO2.

22 DR. KULLER: I think my question is a
23 little bit different perhaps. That was that the
24 concern, at least as I remember and actually was

1 brought to the Board, was the fact that people who
2 had the tests were then being cleared for rather
3 very vigorous exercise and there seemed to be a poor
4 correlation between, as you just pointed out,
5 between what you could do in terms of your fitness,
6 and the probability that doing strenuous exercise
7 might cause a lethal arrhythmia.

8 And I'm not saying that you shouldn't do
9 the fitness. What I'm suggesting is, it seems to me
10 that it's very important to continue that
11 surveillance because one of the recommendations was
12 made, is to look at that surveillance in
13 relationship to a variety of health behaviors, but
14 certainly to reduce the problem.

15 Because much like we've heard about the
16 problem of suicide, when we looked at the original
17 data the rates of sudden cardiac events were not
18 terribly different than in the civilian population,
19 which is totally unstressed in the sense of being
20 not physically fit, but the rates were fairly high
21 and a fair number of these were related to vigorous
22 physical activity. Not so much the exercise
23 testing, but the fact that the predictability of the
24 fitness testing to identify people at risk may not

1 be as good as people think and that there was a
2 false sense of security being developed in a sense
3 that since I did well on the fitness test, I can
4 then basically, as you just pointed out, I can then
5 go out and take off until I drop and collapse.

6 Now, I don't know whether that's true or
7 not.

8 GENERAL HOFFMAN: I think that that's a
9 valid concern and to address that concern, one of
10 the things we tried to do is we're putting together
11 Health and Wellness Centers on each of our bases
12 that will oversee the fitness testing. There will
13 be an exercise physiologist there.

14 It will be one stop shopping for fitness
15 and health promotion and part of the protocol of
16 being tested will be an exercise prescription about
17 the appropriate level of exercise in the future, to
18 give people a more realistic appraisal of what they
19 ought to be doing based on what they've done.

20 DR. KULLER: I would just encourage, again,
21 developing your surveillance. It's very easy to do
22 and it's very unlike our other problems. It's very
23 easy to find these people because they don't move
24 very much after the event. So in reality, you can

1 essentially monitor this fairly closely in all of
2 the services.

3 And I think relating this back to that
4 fitness test, there are other risk factors and
5 especially in relationship to the activity at the
6 time of the event is rather critical to make certain
7 that you're maximizing the benefit of this program.

8

9 And also, it may be very reinforcing to the
10 sense of defining what individuals need to be into
11 your health promotion prevention program in a big
12 way.

13 LIEUTENANT COLONEL PARKINSON: The other
14 comment I wanted to make, responding to Dr.
15 Fletcher's comment concerning anxiety and what we'll
16 call administrative sanctions for people who don't
17 meet the Air Force standard.

18 We have gone, in the Surgeon General's
19 Office, General Sloan particularly, we have gone out
20 of our way to make sure, working with the people in
21 our personnel community, that the standard
22 essentially of the Air Force is participation in a
23 regular aerobic exercise program.

24 We have put in considerable language in the

1 instructions of this program that allows the
2 commander to very, very broad labor authority for
3 that individual who at six months or even a year
4 later, for whatever reason, does not meet Category
5 Level 3, but if he remains participating in an
6 ongoing, i.e., three to five times a week of aerobic
7 exercise and basically can be shown to do that, that
8 that commander has the authority and indeed is
9 encouraged to give that.

10 Finally, the commander with the most amount
11 of experience, and that's General Yates in AFMC, has
12 decreed that no administrative actions will be taken
13 against anyone in his command, unless it's on that
14 one clause of -- that one reason, they are unable or
15 unwilling to participate in a regular aerobic
16 exercise.

17 And if they're unable to participate in
18 regular aerobic exercise, they have another medical
19 condition which would require medical evaluation and
20 the usual medical evaluation and waiver process,
21 MEB, for example, evaluation board that we would
22 have had them undergo, but that's an educational
23 process that we have to continue to work on.

24 Thank you.

1 DR. KULLER: Yeah, Russ has one.

2 DR. LUEPKER: Yeah, I just wanted to follow
3 up. You said, Lou, some of the basic things I was
4 going to say. Not everybody who dies suddenly
5 during vigorous physical activity has not exercised
6 for the last ten years. Many well conditioned
7 people die during this.

8 And I think the opportunity you have
9 potentially, while not using this screening test, is
10 to go back and to have those data and see if you can
11 relate that exercise, controlled exercise, as to
12 some of these people, because I wasn't here two
13 years ago, but we see more reports of healthy people
14 that are running five, ten miles a day dropping dead
15 and we need to learn more about that.

16 LIEUTENANT COLONEL PARKINSON: I might
17 just say parenthetically, we're finding just the
18 converse actually to be kind of true. And that is
19 we've identified several individuals who came to
20 medical attention because they performed poorly on
21 some maximal cycle ergometry and subsequent medical
22 evaluations demonstrated underlying medical
23 conditions that we would not have detected by having
24 them run around a track, so it works both ways.

1 And you're right, we need to collect better
2 data on both of them.

3 DR. KULLER: Okay. Any other questions?

4 Thank you very much, that was very good.

5 We're now going to move on to another topic
6 and this is an Investigation of Reported Birth
7 Defects at Robins Air Force Base, Georgia, by Dr.
8 Robbins, so it's your Air Force Base, I presume.

9 CAPTAIN ROBBINS: Actually, the base is R-
10 o-b-i-n-s and my name has two Bs. I can't claim the
11 base is named after me.

12 DR. KULLER: The Air Force Base only has
13 one B?

14 CAPTAIN ROBBINS: That's right.

15 DR. KULLER: We'll change that.

16 CAPTAIN ROBBINS: Can I have the first
17 slide, please.

18 Colonel Wright, our Division Chief, was
19 saying that all of us at this new organization are
20 wearing two hats, so in my two talks, my first talk
21 I'm listed here as Preventive Medicine Consultant in
22 the Epi-Services Branch. In the next talk I'm an
23 epidemiologist and an officer, so two hemispheres of
24 my brain, I guess.

1 Okay. This first talk, I just want to
2 briefly share with you the results of an
3 investigation that we were called to do down in
4 Georgia.

5 Next slide, please.

6 We did this investigation on the 11th
7 through the 15th of April. We were asked to
8 investigate a possible cluster of poor reproductive
9 outcomes in the 52nd Combat Communications Squadron
10 at Robbins Air Force Base, Georgia.

11 And just a little background, Robbins is
12 one of the bases in Air Force Materiel Command that
13 is a -- they have a big logistics facility there and
14 this particular unit, almost everybody in the unit
15 had spent at least some time in the Persian Gulf in
16 the recent past, just because of the nature of the
17 work that they do.

18 Myself, Majors Susan Mitchell, Russell
19 Eggert from Brooks went. We were handicapped all
20 along in that it was difficult to get some of the
21 information that we needed. We had to use multiple
22 tactics, sometimes even having to telephone some of
23 the patients to get things. We got some
24 information out of the medical records.

1 The labor and delivery log from the
2 hospital was very helpful. We also made use of a
3 data base run by HA called RCMAS and I won't go into
4 what that stands for, but it was very helpful
5 especially in getting information about CHAMPUS and
6 what's called supplemental care.

7 Next slide, please.

8 The 52nd CCS was the squadron that initial
9 went to their commander with these concerns. They
10 are one of four combat communications squadrons
11 within what was known as the 5th Combat
12 Communications Group, which I couldn't quite figure
13 out why, but it's called the 5th MOB, and the 52nd
14 CCS approached their commander who then approached
15 us with information about five quote, unquote,
16 pregnancies that had occurred in 52nd CCS personnel
17 or their spouses, within the previous sixteen
18 months.

19 And this is what they told us and also this
20 information was in the local newspaper. Just in
21 this form. Babies nerves didn't develop in the
22 intestines, a premature birth. We were told eight
23 months gestation. A fetus with posterial urethral
24 valve syndrome, a fetus with polycystic kidneys and

1 a fetus with -- we were just told low hormone levels
2 and that the baby was anencephalic.

3 Next slide, please.

4 So the 52nd CCS was -- the questions they
5 had, do we have a high rate of problems? Obviously,
6 it's a fairly small unit and they were talking
7 amongst themselves, they were speculating on causes.

8 Perhaps the type of work environment that they
9 have, they work with communications equipment, wide
10 band radio frequency equipment.

11 This base apparently had a history of some
12 toxic wastes and, as I say, almost all of these
13 people had been in the Gulf recently. In three
14 cases out of these five, the member or the spouse
15 had deployed and in two cases, there wasn't any
16 history of deployment.

17 And then also, as I said, this information
18 had come out in its raw form in the local newspaper
19 and was generating a lot of attention.

20 Next slide, please.

21 So when we heard about this, we wanted to
22 get detailed information on the cases, of course.
23 Another unit at Brooks was -- had a work site
24 investigation underway, looking at it from an

1 occupational medicine point of view.

2 We wanted to look, not only at this unit,
3 but the other four communications squadrons in the
4 MOB, since they had basically, essentially very
5 similar work place and deployment history, we wanted
6 to look at the rest of the base and we also wanted
7 to see, to compare what we found to national rates.

8 And on the basis of really epidemiologic
9 considerations, we decided to restrict our study
10 population to active duty personnel or their
11 spouses, where one of those two was assigned to
12 Robbins with a known pregnancy outcome between 1
13 January, '92 and 30 March, '94.

14 In other words, this base being where it
15 was, it was close to some other military facilities.

16 Sometimes what would happen is a woman might give
17 birth at the base and say her child might have a
18 problem, but in fact she was a dependent wife of an
19 active duty Navy and it's just that her mother
20 happened to live there in that town and the husband
21 was off at sea, so she just went to the hospital and
22 delivered, and really, no possible etiologic
23 relationship to the base, so we excluded those
24 people.

1 Next slide, please.

2 So the first step was to try to get
3 information about the cases and this was quite
4 interesting because things were not really what they
5 had -- at least they weren't what they were in the
6 newspaper. The first case with the intestinal
7 problem turned out to be a case of Hirschsprung's
8 syndrome.

9 The second case where there was a premature
10 delivery, it was at eight months and eight month
11 gestation, it was an emergency C-section because the
12 mother had developed pregnancy induced hypertension.
13 We talked with the parents and the baby was fine.
14 They couldn't really understand why we were even
15 calling them. They mentioned something about the
16 baby having a milk allergy or something.

17 Case Number 3, this was a documented case
18 of a very severe congenital, multiple congenital
19 anomaly, posterior urethral valve syndrome with
20 Potter's sequence and a very unfortunate situation.

21 Case Number 4 turned out to be a classic
22 case of infantile polycystic kidney disease, which
23 is a well known autosomal recessive disorder, a
24 genetic disease and the parents were aware after

1 this that they had approximately 25 percent chance
2 with each pregnancy. And, you know, any birth
3 defects expert worth their weight in salt, will tell
4 you there's just no possible etiologic relationship
5 between a genetic disease like this and going to the
6 Gulf or anywhere else, working at Robbins or
7 whatever.

8 Case Number 5, this anencephalic case, it
9 turned out that there was a false lab result on the
10 AFB, alpha fetoprotein and -- because the mother's
11 dates were poor and that in fact, when they got her
12 dates right, they found that the AFP level was
13 totally appropriate and had done several ultrasounds
14 and they were all normal, so you know, the newspaper
15 reported this as a case of anencephalic baby and it
16 was a totally normally pregnancy.

17 So in the end, we were left out of these
18 five, with only two cases that were what you would
19 call unexpected or unexplained. Again, as an
20 epidemiologist, to me the third page, the infantile
21 polycystic kidney disease, I just think there's no
22 plausible etiologic relationship, but -- so any way
23 --

24 Next slide, please.

1 That was interesting. The other unit at
2 Brooks that was looking at the work site from an
3 occupational point of view, this was the main
4 conclusions of their report. They also worked with
5 the local bio-environmental engineers.

6 They said exposures to work place chemicals
7 and radio frequency radiation all well below
8 established thresholds and standards and besides,
9 they said, radio frequency radiation is not known to
10 be teratogenic, except possibly at very high levels
11 and they were saying that you basically had to cook
12 a pregnant women in order to cause birth defects
13 with radio frequency they were working with.

14 Next slide, please.

15 Okay, so here's the first -- this is
16 looking at on and off base. We were able to get
17 information as far as pregnancy outcomes on 555
18 pregnancies during that time period that I told you
19 about. You'll see in the following slide the grand
20 total is going to be a little smaller, because we
21 weren't able to get information on the unit that the
22 people were assigned to for all 555, but as far as
23 just the base as a whole.

24 And 94.2 percent of the pregnancies were

1 classified as a normal birth and .5 percent had a
2 major malformation and 5.2 percent had some kind of
3 pregnancy loss, spontaneous abortion, missed
4 abortion and fetal demise. So the base as a whole,
5 one can easily see, does not appear to have any sort
6 of gross problem.

7 Next slide, please.

8 Now, the real question had to do with unit
9 of assignment and what we did was, we took everybody
10 that was in one of the four combat communications
11 squadrons and/or the support for the 5th MOB and
12 lumped them all together in one group, since they're
13 all basically doing the same thing, and compared
14 them to everybody else on the base.

15 And depending on whether you include or
16 exclude that one case of polycystic kidney disease
17 and as an epidemiologist, again, my strong
18 contention is that it should be excluded, but either
19 way, I've presented it here both ways, the
20 probability of having a poor outcome, if you're in
21 that group, was either 8.3 percent or 7.4 percent.

22 Again, the poor pregnancy being a
23 malformation, spontaneous abortion, a missed
24 abortion or fetal demise. And if you were assigned

1 anywhere else on the base it was 6.5 percent.

2 Again, you know, extremely similar and we
3 had 465 people here, simple Chi square test on this
4 two by two table is very, very far from zero and
5 again, people could say well, the power, you know,
6 but this was all the information we could get.

7 We worked with what we had.

8 And again, I don't know, somebody like Ken
9 Rothman would say, you know, P values is not the
10 important thing any way, it's comparing the numbers
11 and so I think the numbers speak for themselves.

12 Next slide, please.

13 So if we break this out, if we again take
14 the 5th MOB, the 51st through 54th Combat Support
15 Squadrons, that group's rate for major malformations
16 was 3.1 percent, their rate for miscarriage was 5.2
17 percent.

18 In the other units on base, we didn't find
19 any major malformations and the miscarriage rate was
20 6.5 percent. So the group was correct, their
21 initial concern, that they had major malformations
22 in their group and nobody else on base did. They
23 were correct. They had two and nobody else on base
24 did.

1 However, their rate, as you see in the next
2 slide -- next slide, please. The problem was that
3 their rates were no different than what would be
4 expected in the general population, so I think again
5 -- we tried to do it two different ways.

6 One was are they different from other
7 people on base, but again the ultimate bottom line
8 is, is this something that would be unexpected? I
9 think both questions are important.

10 U. S. national rates, we talked to experts
11 at the CDC and this was what they gave us, major
12 malformations you'd expect about three percent and
13 some people say up to six. We went with the
14 conservative number.

15 Minor malformations, which we didn't see
16 any, three to four percent. Premature deliveries,
17 anywhere from five to ten percent. As I say, we had
18 one. I didn't calculate a rate for that. And
19 miscarriages, anywhere from ten to twenty percent
20 and we're looking at five, six, seven percent here
21 in this study.

22 Next slide, please.

23 So our conclusions, these data do not
24 support an association between unit of assignment

1 and risk of poor pregnancy outcome at Robbins Air
2 Force Base. These data do not indicate that rates
3 for malformations or miscarriages are unusually high
4 within units or base-wide and that essentially these
5 two unexplained bad pregnancy outcomes in the 52nd
6 CCS were a random clustering of events, not anything
7 inconsistent with national figures.

8 Is there any -- one more slide? Okay, next
9 slide.

10 We consulted with CDC teratology experts.
11 They agreed with our analysis and their assessment
12 was a no true cluster, I mean in the etiologic
13 sense, exists. A similar study of Gulf War veterans
14 which was -- preliminary results were presented at
15 the NIH Persian Gulf meeting recently found
16 basically the same thing, there was no increased
17 risk of poor reproductive outcomes in the
18 Mississippi Guardsmen.

19 We went back to the newspaper and said hey,
20 you've got it wrong. Here's the true information
21 and we educated them and they were very responsive.
22 They immediately published a new article, which we
23 checked for factual correctness and was quite
24 accurate.

1 And we gave recommendation to the base for
2 ongoing surveillance of reproductive outcomes versus
3 unit of assignment, just because it was such a
4 horrendous pain trying to get all this data post
5 hoc, and we thought if this was going to continue to
6 be a question, that they should set up a
7 surveillance system.

8 Thank you. I'll take any questions on this
9 before I give the next talk. Yes.

10 DR. ASCHER: Mike Ascher. One of the
11 problems like this that's been beat to death is the
12 issue of clusters of cancer and various things, and
13 birth defects.

14 Some of our people in California --

15 VOICE: It's hard to hear you back here.

16 DR. ASCHER: I'm sorry. One of the things
17 that's been beat to death is looking for these
18 clusters or pseudo-clusters in cancer and birth
19 defects, and the people in California that work on
20 this have sort of looked at it a different way,
21 which is kind of fun to think about.

22 And that is if you have a known rate for
23 something, for a whole population, and then you have
24 a sample size of whatever you have, what is the

1 expected frequency of an event of a certain size.

2 In other words, what is the range of normal percents
3 that you would have and in many cases, based on that
4 distribution, you don't need the case control study.

5 Because what it is saying is, if the actual
6 rate is something that is higher than you would
7 expect, then this should not be the only one. You
8 should expect lots of clusters.

9 So in other words, as used in the EMF
10 studies, the electro-magnetic field studies, the
11 prototype school in California that had these
12 cancers, the issue was if this was the rate of
13 increased risk of this phenomenon, what was the
14 probability of finding -- how many schools would
15 there be in California that had the same or higher
16 risk?

17 And it turned out there should have been a
18 hundred. And so you can calculate backwards and
19 say, if you found the tail and there are no other
20 ones, you know you found the tail. So I mean that's
21 the logic and it's sort of an interesting way to
22 think about these data and so you just do it
23 backwards.

24 CAPTAIN ROBBINS: One of the things that we

1 found, we went in and we wanted to meet with the
2 people from the squadron, so we asked the First
3 Sergeant's from the squads to come and we spoke
4 directly with them.

5 And one of the things we were trying to
6 communicate, which was sort of a concept that they
7 hadn't thought about was that these things are not
8 totally unexpected. It seemed strange to them when
9 it happened, but we were trying to explain to them
10 the concept that, you know, you expect some of these
11 things to happen at a certain rate.

12 And after we explained that, it was very
13 helpful for them, they were able to grasp, they were
14 able to grasp that concept.

15 Any other questions?

16 DR. ENGLELEY: Were the two cases associated
17 with Gulf Syndrome?

18 CAPTAIN ROBBINS: Can you pull out that
19 slide that has what the five cases were? I want to
20 make sure I recall the right thing here.

21 Three of the cases, there was a history --
22 okay, Case Number 1, the documented Hirschsprung's
23 syndrome, that one the woman herself who had the
24 baby, she deployed to the Gulf.

1 The second case with the premature birth,
2 the husband deployed.

3 The third case, the husband deployed.

4 Case Number 1 and Case Number 3 are the
5 ones that I'm calling real cases and in both of
6 those the -- Case Number 1 the member deployed, Case
7 Number 3 the husband deployed, so the answer to your
8 question, yes, there was deployment in those cases.

9 Okay, if there's no more questions on that,
10 I'll move on to my other hat.

11 I think this is sort of the kind of thing
12 that we're trying to do at OPHSA in this talk. What
13 I want to do is walk you through sort of a Health
14 Services approach to a screening program, which has
15 been implemented throughout all of the services to
16 look for blood lead poisoning in children.

17 Next slide, please.

18 Just a little background on this. This
19 program was mandated by Congress in response to the
20 CDC's 1991 publication Preventing Lead Poisoning in
21 Young Children, which we affectionately call the
22 Green Book and you probably have all seen it.

23 They just picked a couple of quotes here
24 from that publication in which they stated childhood

1 lead poisoning is one of the most pediatric health
2 problems in the U.S. today, and the goal which they
3 laid out, was to reduce children's blood levels
4 below 10 micrograms per dl and, as you all remember,
5 that was revised downward quite a bit from the
6 previous action level which had been 25 for a while.

7 They -- as far as how to accomplish this,
8 their recommendation was for universal screening and
9 again, here the quote.

10 "Universal screening is recommended, except
11 in communities where large numbers or percentages of
12 children have been screened and found not to have
13 lead poisoning."

14 Now, in the Air Force it was not the case
15 at the beginning of this program that large numbers
16 of children had been screened, so one could not say
17 whether we did or did not have a problem at the
18 beginning of this program. So therefore, the
19 program was implemented.

20 Next slide, please.

21 The 2nd of April, 1993, the Surgeon General
22 of the Air Force sent out a policy letter and in
23 which it was stated that there would be, universal
24 screening at the world child visit at age 1 and that

1 there would be targeted screening, in other words,
2 by the use of a questionnaire. And if the parent
3 answered yes to any one of several questions on the
4 questionnaire, then the child would get the test.

5 And this was basically because some
6 children were going to be seen after the age of 1
7 and they wanted to try to catch them up through age
8 6. The bases were given the option of either
9 testing all available children, all eligible
10 children, or they could test 20 percent per year and
11 phase it in until they were testing a hundred
12 percent.

13 That was in April and then in the summer of
14 1993, I began to receive the first data from the
15 bases, the Air Force Bases.

16 Next slide, please.

17 In the first reporting -- the idea was that
18 this was supposed to be a quarterly reporting, but
19 of course in the beginning of the program we had to
20 kind of get everybody in sync and it turned out that
21 some bases had anticipated this and had already
22 started doing some testing in calendar year '92.

23 And so what we did was, we told all the
24 bases, everything you have up through the end of

1 fiscal year 1993, send that to us and we'll call
2 that the first reporting period. So some of the
3 bases started when the policy letter came in April
4 and some of them had gone n November of '92 they
5 were testing. And then after that, we went to
6 quarterly testing.

7 Next slide, please.

8 I know this is kind of busy here. The
9 bottom line was that during the -- let's see here.
10 This is -- this one is out of order. You need to
11 find one where it says up through 30 September, '93.

12 Somehow I got them mixed up.

13 There's a series of three of these slides
14 containing a lot of data for the three reporting
15 periods. Okay, here we go.

16 So this is the first reporting period.
17 There was a total of 13,401 children tested and
18 there was a total of 171 children that had levels
19 that would be considered positive, greater than 10,
20 for a positivity rate of 1.28 percent.

21 And as you can see here, the great majority
22 of the positives were in this 10 to 19 range, with
23 only eighteen out of this 13,000 being above 20, and
24 the levels above 20 which will require medical

1 attention. In other words, a physician has to
2 evaluate the child at that point.

3 Okay, next slide, please.

4 We had a major problem with the first
5 reporting problem, which wasn't anticipated, but we
6 had to deal with it. Some of the bases were
7 confused about which test to report. The policy
8 letter said that they were allowed to use a
9 capillary finger stick as an initial test if it was
10 confirmed.

11 And the idea that the writers of the letter
12 had was, of course, that even if more than one test
13 was done, that it should all be considered to be one
14 case and be reported as one elevated level, but some
15 bases were reporting that they did a capillary stick
16 and that was elevated and maybe they did another
17 capillary stick and then finally they did a venous
18 test and they'd report all three, so you may have
19 one kid, but there's three positives coming out of
20 that one case.

21 So the implication is that this 1.28
22 percent, as low as it is, is probably an over-
23 estimate.

24 Next slide, please.

1 So the second reporting period, the last
2 quarter of calendar year '93, guidance had been
3 issued from the Surgeon General's Office to report
4 only venous test results.

5 Next slide.

6 And this time around, we had a smaller
7 number of totals because this is a more -- this is
8 just a three month period and it doesn't extend
9 back. And 7,339 children tested during this period.
10 98 positives for a positivity rate of 1.34 percent.

11 So even though we had given guidance on
12 this, the number was actually slightly higher and
13 again, the vast numbers of positives are in this 10
14 to 19 range with a few in the 20 to 44 and nothing
15 ever higher than that.

16 And most of the -- a pattern that you may
17 observe here is that most of the positives are off
18 base, which has implications for trying to do
19 something about it.

20 Next slide, please.

21 Now, we identified another problem. I felt
22 like I was kind of a fly in the ointment because I
23 kept calling up to Washington and saying oh, can we
24 send out a letter about this too?

1 Here's another problem. Kids that were
2 identified in the first reporting period, of course,
3 were receiving follow up tests, which they should.
4 But bases were reporting these elevations as if they
5 were the same thing as a newly identified test.

6 So it sort of -- there was a group that was
7 kind of being perpetuated through all the reporting
8 periods and being added to whatever new cases came
9 along. So you were sort of getting this rate
10 inflation, which meant that this 1.34 percent in
11 this period was also probably an overestimate.

12 And it caused people to see that tracking
13 something like this positivity rate, as it was being
14 used, was going to be very difficult. If the number
15 went up, one would have a very hard time knowing
16 why, what that meant.

17 Next slide.

18 So the guidance was issued to report only
19 test results from new cases in each reporting
20 period.

21 Okay, next slide, please.

22 So the third reporting period that went for
23 the first three months of this year, I believe these
24 numbers as an epidemiologist, and we did 6,874

1 tests, 62 positives for a positivity rate of .9
2 percent.

3 Now, some of you may be familiar with some
4 of the numbers that were in the Green Book, talking
5 about testing being done in Baltimore and Chicago
6 and I mean some of these numbers -- I hear them on
7 the radio too. I'm driving down the road and I
8 hear, you know, the Environmental Protection Agency
9 has determined that one out of every six children is
10 lead poisoned. Well, that depends on where you
11 are and in the Air Force, it isn't true. .9
12 percent, I think, is probably good. It's not 20
13 percent or 30 percent.

14 Next slide, please.

15 So I think this is the only one of the
16 three reporting periods without overestimating bias.
17 I think it gives a good answer to the Public Health
18 question, how serious is the problem of lead
19 poisoning in Air Force dependent children.

20 And the answer is about .9 percent of Air
21 Force children have blood levels above 10. It's a
22 very low positivity rate and it is markedly below
23 civilian findings.

24 And I think what's even more striking about

1 this extremely low positivity rate is how many of
2 the bases that -- again, this program was mandated
3 on them, but how many of these bases are doing this
4 test quarter after quarter and yet are finding no
5 positive tests?

6 And of the data from the third reporting
7 period, 89 bases reporting worldwide, 63 percent of
8 the basis did not even have one elevated result.
9 And of the bases that did, over half of them had
10 only one elevation. And we have one base, you know,
11 at the extremes that had 7.

12 Next slide, please.

13 Just look at some policy implications,
14 since that's sort of what we're trying to do at
15 OPHSA, go a little bit beyond just the surveillance.
16 Let's say that it costs \$17 to do a test. The cost
17 of the 27,614 tests done to date is \$469,438, so the
18 cost for one positive test is almost \$1,500.

19 Now, that may seem, you know, like a lot of
20 money, but these costs are nothing compared to a
21 civil engineering program, which is called the Lead
22 Based Paint Program. And just during four months of
23 1993, the cost for the Air Force to run this lead
24 based paint program was over \$13 million, just

1 during a four month period.

2 And keep in mind that only structures that
3 are on Air Force Bases are impacted by this, so I
4 went back and I looked at, you know, where I said we
5 have .9 percent positivity overall, and over two
6 thirds of those very small number of positives were
7 off base. So \$13.6 million being spent for a
8 program which, from a Public Health point of view,
9 can have very, very, very small impact.

10 Next slide, please.

11 So I want to go back to the CDC's original
12 words and once again, they said:

13 "Universal screening is recommended, except
14 in communities where large numbers or percentages of
15 children have been screened and found not to have
16 lead poisoning."

17 And the Surgeon General's Office asked us
18 to look at this program, evaluate it and we wrote a
19 technical report and in our technical report from
20 OPHSA, we said the Air Force is certainly an example
21 of such a community.

22 So our main recommendation was to request
23 the Assistant Secretary of Defense in Health Affairs
24 to allow cessation of universal screening at bases

1 which test all eligible children and find no
2 elevated levels. We can't see any Public Health
3 rational for continuing to do universal screening.

4 Next -- oh, no more. Okay, I'll entertain
5 questions on this non controversial presentation.
6 Okay, in the back there.

7 VOICE: I don't know anything about lead in
8 children other than it seems to be a bad
9 combination, so my question is just going to be
10 informational.

11 It's interesting that when I look through
12 the data you presented, your largest numbers in the
13 11 to 19 range are all in the zero to 2 year old
14 cell and the timeframes being reported are times of
15 years when that age child is unlikely to be outside.

16 And so my question is that thought they
17 were reported during the winter months, were the
18 tests actually carried out during the summer months
19 when kids that age might be outside and I gather
20 they eat the dirt or something to get lead exposure?

21 CAPTAIN ROBBINS: Well, lead can also be in
22 water and that's a major source that's been
23 identified, so that wouldn't necessarily involve the
24 child going outside, you know, to eat dirt.

1 And the other thing is that we actually
2 don't know when these tests were done. All I know
3 is when they were reported to me. They could have
4 been done in the summer and the result didn't come
5 back until the winter time.

6 VOICE: Regardless, it certainly doesn't
7 seem that there's any problem. I was just curious.

8 CAPTAIN ROBBINS: Right, right. Okay, next
9 to him.

10 VOICE: I'm with the Texas Department of
11 Health. We have many communities that are doing the
12 same kind of testing and asking us to do the same
13 kinds of considerations that they no longer have to
14 do this.

15 I guess my question was brought on by one
16 of your statements almost at the very end, that the
17 program, the lead abatement program is \$13 million
18 that I thought you said shouldn't be spent. And
19 maybe we would look the other way around and say
20 maybe it's been successful.

21 Is this a program that has been in the past
22 or is this a program that's just now in place?

23 CAPTAIN ROBBINS: It just now -- it just
24 recently started. It started during the months that

1 I showed you, I think, which was the beginning of
2 the program.

3 VOICE: I tend to agree with you then, if
4 there's not a problem.

5 CAPTAIN ROBBINS: Captain Berg.

6 CAPTAIN BERG: Berg, Navy. Your conclusion
7 as to cease testing on the basis that they had no
8 elevated levels, does that mean that your number of
9 cases, 56 bases, or are you going to allow an
10 occasion case?

11 CAPTAIN ROBBINS: In the technical report,
12 we actually gave -- we said that -- to us no cases
13 could either mean that they had tested all eligible
14 children and found zero. We tried to pick the most
15 non controversial recommendation, so we figured --
16 and I asked -- I called the people at the CDC that
17 run the lead screening surveillance branch and I
18 said, let me give you a hypothetical situation, a
19 town, a base test and they find zero cases. Do they
20 have to keep doing universal screening?

21 They themselves said that sounds reasonable
22 that they wouldn't have to keep doing that. They
23 could do target screening with questionnaires. So
24 if the CDC agreed with it, we figured that it was

1 probably going to be okay for us to recommend that.

2 We also knew that some bases would not be
3 testing all children, they might test a sample. And
4 so we gave a confidence interval around which -- or
5 if their result was no higher than, I think it was
6 one per thousand from their sample, we said that was
7 basically the same thing as zero and that they could
8 consider to not keep doing testing.

9 So we tried to again run it by the people
10 at the CDC and get some agreement from them before
11 recommending anything.

12 Colonel Parkinson.

13 LIEUTENANT COLONEL PARKINSON: I just want
14 to make a general comment on Tony's presentation and
15 it's something that putting ourselves at the base
16 level, Military Public Health Officers or clinic
17 administrators or hospital commander's job, we're
18 now looking at the TB OSHA compliance regulation
19 that once again, is based on what has been an inner
20 city HIV infected population that has had multiple
21 drug existent TB spread to health care providers.

22 In the military system, we screen everybody
23 for HIV. Our tuberculosis rates are well at and
24 below the national prevalence for tuberculosis and

1 yet we, as other health care providers, have to
2 march along to what continues to be a categorical
3 approach to toxins, to exposures to infectious
4 diseases that are coming out of our well meaning
5 Federal agencies, including Public Health Service
6 where I just spent two years.

7 And it seems to me that one of the things
8 that might be useful for the AFEB to do is to think
9 in the global sense of how we can make sense of
10 categorical programs that hit that poor Military
11 Public Health Officer and that Hospital Commander
12 who have got to balance what are increasingly
13 limited resources.

14 The Defense health plan, I understand,
15 through FY'95, is \$7 billion short of requirements
16 at this point and we're leveraging more requirements
17 for blanket screening programs that are neither, at
18 least in many of our populations, just don't make
19 sense from a Public Health approach.

20 And what we're doing with this report is
21 working it up through a certain General's Office to
22 bring to our Surgeon General to perhaps DOD's
23 attention and say, there's got to be a better way
24 and is there a way that we can work more proactively

1 perhaps with legislation, put in amendments where
2 necessary or work with other Federal agencies to
3 take perhaps a more targeted, focused approach
4 around these areas?

5 It's not -- this is one of many issues that
6 we deal with daily from a policy standpoint,
7 particularly in the environmental area. I might
8 remind you, those numbers, that 13 million, that was
9 for four months so you could take that times four.

10 CAPTAIN ROBBINS: Those were just four
11 months.

12 LIEUTENANT COLONEL PARKINSON: That's
13 right. And that's a concern. If there's anything
14 we could do along that --

15 DR. KULLER: I think that what you've just
16 presented is an excellent report which basically can
17 lead to a reasonable decision and recommendation. I
18 think that what we need to do is to provide the data
19 to the Board, ask the Board to make a recommendation
20 back to you about what to do.

21 We'd be glad to do this, I think, if you
22 want us to make a recommendation on the lead
23 program, based on the data which has been presented,
24 I think the Board would be glad to. I think this is

1 an excellent way of answering the question you just
2 raised.

3 The only way we can answer the question is
4 with some data, and you presented the data and
5 clearly, the data, at least what we see, is
6 reasonably persuasive, at least to me, in terms of
7 what's going on and especially with the abatement
8 program, which probably makes no sense at all.

9 DR. BROOME: Well, I guess, first of all,
10 actually this other data, I'd like to see. I'd like
11 to know how many children have been screened at each
12 of the bases before you conclude that zero cases
13 identified means something, particularly when you're
14 expecting an overall rate around one percent, you
15 need to have screened several hundred children.

16 I'm assuming that's happened at each of the
17 89 bases.

18 CAPTAIN ROBBINS: I can tell you, just from
19 talking with the people on the phone, that most of
20 the bases chose to go ahead and just screen a
21 hundred percent, and the reason why was because in
22 the policy letter, it was sort of held out to them
23 that perhaps if they tested all their kids and
24 didn't find any elevations, that maybe there might

1 possibly be some relief from the program down the
2 road.

3 So a lot of them kind of looked at that and
4 said oh, let's just test everybody and get this out
5 of the way. So the numbers really do -- they sort
6 of approach universal screening.

7 DR. BROOME: What's the average number of
8 children per base?

9 CAPTAIN ROBBINS: I'm sorry, I couldn't
10 tell you that.

11 DR. KULLER: It's in the hundreds.

12 DR. BROOME: But it would have to be
13 multiple hundreds to reliably exclude a one percent
14 rate.

15 CAPTAIN ROBBINS: It really varies. Some
16 of the bases are very large, some are very small and
17 --

18 DR. BROOME: I think it would also be very
19 helpful to see the positivity rates by base, because
20 you've got some bases possibly with fairly
21 substantial rates. The seven person base.

22 DR. ASCHER: My comments earlier. If this
23 whole system is driven by the base that has seven,
24 then you have that problem I talked about, how do

1 you calculate what's the expected frequency without
2 these other numbers.

3 DR. BROOME: Yeah. I mean, I think that
4 would be more helpful information and it might help
5 you target there may be a place where you do want to
6 do abatement, as well as places where you want to
7 stop screening.

8 CAPTAIN ROBBINS: That was why our
9 recommendation was very carefully worded that only
10 bases that had gone through and done all the testing
11 and found zero and consistently, that they would be
12 the ones that could put in a request to get some
13 relief from the program.

14 DR. BROOME: The other thing is I don't
15 know -- I think reasonably soon the data will become
16 available, showing that there's been a substantial
17 decrease in blood levels in many populations.

18 I think this will be helpful in terms of
19 generally targeting screening to the groups where
20 there really is a problem and I think that's
21 something we'd all like to see.

22 DR. CHIN: Just a simple question. Is the
23 child screening program independent of the lead
24 based paint program?

1 DR. ROBBINS: Yes, they are totally -- one
2 of them is run by the Medics and the other one is
3 run by the civil engineers.

4 DR. CHIN: Two true unrelateds.

5 CAPTAIN ROBBINS: Right. The abatement
6 program -- I guess the way you could think of it is
7 the abatement program treats a house and has its
8 object of concern as a house or a structure and the
9 other program has the child as its object of
10 concern.

11 DR. FLETCHER: Is the source both paint and
12 pipes or lead paint and lead pipes both or what is
13 the source of the test and is the abatement directed
14 at both that, both those things?

15 CAPTAIN ROBBINS: I only know about the
16 program that's directed towards the paint and I know
17 that in that program they go and inspect all the
18 structures on a base and they look for the paint, if
19 it's peeling or chipped and then they test it.

20 If the paint is in tact, then supposedly
21 the structure doesn't need to have anything done to
22 it. So I don't know what they do --

23 DR. FLETCHER: Hold it. I'm an internist,
24 I'm not in pediatrics. I know kids eat lead paint.

1 Is that how this is happening or are there other
2 mechanisms?

3 CAPTAIN ROBBINS: Some of it is through the
4 water, some of it is through eating the soil, some
5 of it is through the paint, some of it is the
6 parents may have certain hobbies, like working with
7 pottery or maybe their occupation, maybe the dad
8 works in a garage and brings home some chemicals on
9 his clothes.

10 So there's multiple sources of exposure.

11 DR. KULLER: You may know that in the State
12 of California, it's required that in any place where
13 they fire a weapon, they must have a warning about
14 potential risk of lead poisoning from the lead in
15 the bullets, and this is -- I have nice pictures of
16 this from stores in California where the California
17 equivalent of the EPA has issued this.

18 So you might use the money to put signs up
19 around the bases about the potential risk of lead
20 poisoning associated with firing of weapons.

21 CAPTAIN ROBBINS: Dr. Blackwood.

22 DR. BLACKWOOD: There are some doctors that
23 do firing and none of them had elevated blood
24 levels, so from our point of view, that's not even a

1 problem.

2 DR. KULLER: You might tell the State of
3 California that, because they have some rather
4 interesting signs in their gun stores. They're not
5 too worried about getting hit by the weapon, but by
6 the lead poisoning.

7 DR. BAGBY: We had just the opposite
8 experience in Missouri however, where the Missouri
9 State Highway Patrol with an indoor range and we
10 found some very high blood levels among the State
11 Highway Patrol.

12 CAPTAIN ROBBINS: Right. I think -- that,
13 to me, I think is the goal. I don't think we can
14 have some kind of broad statement that says this
15 entire program is good or bad. I think it has to be
16 looked at on a base by base basis.

17 MR. DALE: Jim Dale, Air Force. There's a
18 very detailed plan used in x-ray examination of
19 paint surface based on ages of buildings and
20 everything like that.

21 Furthermore, water from these older
22 buildings and households was taken and samples for
23 heavy metals and there's been a very detailed
24 environmental analysis for lead in water and in

1 surfaces and in buildings, and this was all figured
2 out in a very detailed plan.

3 So dirt moving and paint and asbestos
4 continues to require the money.

5 DR. KULLER: But I think if you, you know,
6 make a request to the Board for about -- regards to
7 the lead program, we'll be glad to respond.

8 CAPTAIN ROBBINS: Okay, thank you.

9 DR. KULLER: Thank you very much, that was
10 very good.

11 The next presentation will deal with the
12 Army Serum Bank Repository. I think some of you
13 received a letter about this or some discussion
14 about this and Lieutenant Colonel Kelley will
15 present.

16 LIEUTENANT COLONEL KELLEY: Thank you very
17 much.

18 Good afternoon. I would like to brief the
19 Board this afternoon on the Army-Navy Serum
20 Repository. This repository is the largest
21 collection of catalogued sera in the world and has
22 tremendous potential for use in both operational and
23 research epidemiologic studies. Unfortunately, the
24 funding for its continuation is currently in

1 significant jeopardy.

2 The purposes of this briefing are
3 threefold. First, I would like to inform you about
4 this uniquely powerful asset and how it has been
5 used in the past and how it could be used in the
6 future.

7 Secondly, I'd like to solicit your formal
8 encouragement for the further investment of
9 resources necessary to maximize its potential
10 contributions.

11 And thirdly, I'd like to solicit any ideas
12 you may have to resolve major issues, such as the
13 expected withdrawal of current funding.

14 The Army-Navy Serum Repository, which we
15 refer to as ANSR, consists of about 12 million
16 catalogued sera specimens. The specimens are excess
17 sera from various military contract HIV screening
18 programs, going back as far as late 1985.

19 The credit for the visionary idea of
20 creating this resources goes to Colonel Don Burke
21 and others in the Division of Retro-virology at
22 WRAIR. It was their foresight which required that
23 the excess sera from the HIV screening programs be
24 held initially by the contract labs, and starting in

1 1989, transferred on a quarterly basis to long term
2 storage at a facility in Rockville, Maryland.

3 This is one just aisle in one of the large
4 walk in freezers at the contractor's Rockville
5 facility. The freezers are kept at minus 25 degrees
6 Centigrade. It was economically prohibitive to try
7 to save all of these sera at minus 70, though those
8 that are doubly HIV Elisa positive or Western block
9 positive are kept at the same facility at minus 70.

10 This is a state of the art facility. There
11 are numerous redundant systems. These are just the
12 back up generators in case of power failures. There
13 are also redundant alarm systems and back up spare
14 parts on site for the freezers, so that they can be
15 repaired at any time of day or night.

16 In general, each specimen consists of
17 approximately 2 cc's of sera. There's a handout
18 that was on the table outside the door that gives
19 you some general feel for how these sera break down
20 by source and by year of accession.

21 You'll note that in 1986, it appeared that
22 there were no active duty Army sera and about
23 750,000 recruit applicant sera. Those included both
24 active duty and recruit applicants, but they were

1 categorized, for various reasons, under recruit
2 applicants.

3 The samples arrive at the storage facility
4 on a quarterly basis, as I said, in a satellite
5 monitored freezer truck that comes up from the
6 several commercial contractors the military uses for
7 HIV screening.

8 After arrival, they are catalogued using a
9 double data entry process. Data from each tube is
10 entered by two individuals and the differences noted
11 by the computer are reconciled.

12 While specimens are handled outside of the
13 freezers, they are kept on a bed of dry ice to
14 reduce the risk of freeze-thaw cycles. The tables
15 between these two data clerks is actually a dry ice
16 table and, again, that's to prevent freeze-thaw or
17 at least reduce the problem of freeze-thaw.

18 This computer screen documents the
19 information in the catalogue on each specimen. In
20 addition to the specimen number, the catalogue
21 contains the approximate draw date, the specimen
22 volume, the testing program which generated the
23 specimen, and the location of the specimen within
24 the repository down to the row and column within a

1 specific box, and there's also a section for
2 comments on the use of that specimen.

3 Back to this slide.

4 By reference to other data bases that
5 contain both the specimen number and personal
6 identifying information, it is possible to retrieve
7 most of the specimens collected since 1989.
8 Obtaining specimens collected between 1985 and 1989,
9 requires reference to archived hard copy laboratory
10 manifests.

11 This serum repository is not an inexpensive
12 undertaking. To transport and catalogue the roughly
13 one and a half million specimens added to the bank
14 every year, it costs about eleven cents per sample
15 or a total of about \$300,000.

16 The charge to have a specimen withdrawn and
17 aliquoted into about four subsamples will be by the
18 contract for Fiscal '95, \$165.25. Just to maintain
19 a static bank, that is one with no additions or
20 withdrawals, costs over half a million dollars a
21 year.

22 The bank, as impressive as it may appear,
23 is worthless without the potential to correlate the
24 specimens with other data. The key supporting data

1 source is the data bases that make up the U. S. Army
2 HIV Data Systems or USAHDS, which is described under
3 the top paragraph.

4 The USAHDS data bases include specimen
5 numbers, personal identifiers and a considerable
6 amount of demographic data on triservice recruit
7 applicants in both active and reserve component Army
8 personnel.

9 By using USAHDS specimens, one can link
10 these sera with triservice hospitalization data
11 bases, with the Department of Defense Centralized
12 Automated Tumor Registry, known as ACTTAGR, with
13 military disability data bases, and with Veterans
14 Administration data bases.

15 Mechanisms need to be worked out to link
16 the 2.3 million active duty Navy sera in the
17 collection with various data bases, though we
18 concurrently link sera from Navy and Air Force
19 recruit applicants by going to the supporting data
20 bases.

21 I have listed here some of the past and
22 current uses of the Army-Navy Serum Repository.
23 Lieutenant Colonel Jim Eagan and others at WRAIR are
24 now writing up a study that they did of the

1 seroprevalence of antibodies to hepatitis A, B and
2 C. Their population was about 60,000 recruit
3 applicants and active duty personnel, and the
4 genesis for that study was to help make various
5 policies with respect to hepatitis C infected
6 personnel, and also to provide various baseline data
7 in policy decisions relating to the use of the
8 hepatitis A vaccine, which is going to be,
9 hopefully, licensed soon.

10 I have used the bank to explore the
11 occupational risk of hepatitis C in Army orthopedic
12 surgeons and oral surgeons.

13 It's also been possible to develop
14 carefully defined stratified random samples of
15 recruit applicants from different points in time to
16 document changes in susceptibility to diseases that
17 are important to the military, such as
18 susceptibility to measles and rubella.

19 We currently spend several million dollars
20 immunizing recruits against measles and rubella,
21 when the vast majority of them are immune to those
22 viruses. And I have been able to show that since
23 1989 in these serial samples, that the
24 seroprevalence of immunity is rising and probably

1 reflective of the two dose immunization policies
2 employed in the civilian sector for high school and
3 college students.

4 Another example of the unique capability of
5 this bank was that last summer, when issues relating
6 to Haantan virus were very much on the table, within
7 just a few days we were able to identify a thousand
8 sera from people who came from the Indian
9 reservations in the Southwest where this was a most
10 acute issue, and these were selected and tested for
11 Haantan virus antibodies.

12 The Army-Navy Serum Repository has also
13 been used to look at long term titer levels in
14 persons who participated years ago in pre-licensure
15 Japanese encephalitis vaccine studies. Many of
16 these individuals had become otherwise lost to
17 follow up, and it was possible, using this bank, to
18 get recent sera on them and develop information
19 relating to the timing of booster doses.

20 How often would one, for example, need to
21 be boosted. A similar question could be asked for
22 meningococcal disease, though I believe some of my
23 Air Force colleagues have recently published some
24 data on that.

1 Pertinent to some of the discussions
2 earlier this afternoon, an important capability of
3 this system is to highlight the possibility of
4 supplying pre-deployment sera on persons who may
5 deploy to places like Saudi Arabia or Somalia, and
6 subsequently develop some sort of health problem.

7 Based on past work with the bank, we are
8 confident that most of those who've deployed to
9 Saudi Arabia or Somalia, have a pre-deployment
10 specimen in the collection.

11 The bank is also invaluable for nested case
12 control studies. For example, one study that I'm
13 currently pursuing is a program project grant in
14 which an application is being submitted to the
15 National Cancer Institute to study the epidemiology
16 of lymphomas.

17 This project involves collaborations with
18 Harvard, the University of Pittsburgh, Johns
19 Hopkins, the University of Uppsala in Sweden, the
20 Serum Institute in Copenhagen, and the Walter Reed
21 Army Institute of Research.

22 We've been able to find information that
23 suggests that the bank, within a few years, will
24 contain approximately 200 sera on people who have

1 subsequently developed Hodkins Disease and
2 approximately 300 sera on individuals who have gone
3 on to develop non Hodkins lymphomas.

4 This is clearly the largest collection of
5 prediagnostic sera in the world for this sort of
6 study. Other people have proposed to me studies,
7 for example, to look at the association between SV40
8 antibody and prediagnostic sera in the subsequent
9 development of mesotheliomas

10 There are several issues that we're
11 currently trying to resolve and for which I
12 certainly solicit your ideas. Currently the funding
13 for ANSR is drawn entirely from the HIV research
14 budget. Though there are still HIV research
15 applications for the serum repository, the current
16 uses of the bank are largely not HIV related.

17 We've been told to expect the withdrawal of
18 these funds, possibly as early as the next fiscal
19 year, in light of the shrinking budget for military
20 HIV research. We would like to identify Department
21 of Defense and non Department of Defense sources of
22 core funding.

23 It would seem logical that since the data
24 base and serum repository can serve both operational

1 and research purposes, Department of Defense funding
2 should come from both the operational and research
3 side of the house.

4 In addition, we hope to bring in
5 supplemental funding through charges associated with
6 projects such as a lymphoma program project grant
7 that I described. Use of this resource costs more
8 than just banking the sera and withdrawing it for
9 aliquoting.

10 There's clearly a needed administrative
11 component to coordinate studies and this will be
12 especially critical if the goal is to coordinate
13 enough studies to justify the high expense of the
14 bank.

15 We hope to address some of this need for
16 infrastructure through a Center for
17 Seroepidemiologic studies which will be part of the
18 new Army Preventive Medicine and Wellness Center.
19 The most recent staffing plan for the Center
20 allocates three persons to this general
21 administrative effort.

22 There will still need to be a joint
23 partnership though between the medical research
24 development logistics and acquisition command and

1 the Preventive Medicine and Wellness Center.

2 Because the Preventive Medicine and
3 Wellness Center will have an operational focus and
4 many of the applications of the repository are
5 research applicants, it is anticipated that research
6 management issues, including scientific and human
7 use reviews would best be managed through the
8 research side of the house, along with execution of
9 those studies that are totally classified as
10 research.

11 There are other administrative and legal
12 and ethical issues too. Historically, these have
13 been worked out successfully through the usual
14 channels, but putting the sera to non military uses
15 complicates the issue. Access procedures are being
16 formulated, but determining how to allocate overhead
17 charges to users is proving to be a challenge.

18 Certainly what people -- what investigators
19 would be willing to spend to obtain access to a
20 hundred sera on diseased patients, is different from
21 what they feel would be reasonable to obtain access
22 to sera that are on a hundred random individuals.

23 Bringing in non DOD funding to support
24 specific studies, adds a complicating bureaucratic

1 element. To hire persons for studies funded by non
2 military sources, we've been exploring the use of
3 standing task order contracts, channeling funds for
4 personal services through organizations such as the
5 Jackson Foundation or the American Registry of
6 Pathology, which is affiliated with the AFIP, and
7 having on site support staff actually in the employ
8 of collaborating academic institutions.

9 For example, an individual who might be on
10 site to help manage the study at Walter Reed, would
11 actually work for Harvard or Johns Hopkins or
12 whatever.

13 So in summary, our plans for further
14 development call for expanded uses of the serum
15 repository to meet broader military and civilian
16 needs. The extension of access to outside
17 institutions is felt to be desirable, both to
18 advance epidemiologic science and, quite frankly, to
19 generate funds.

20 Such a plan necessitates a more formal
21 infrastructure than has been the case up until now.
22 We anticipate this infrastructure being jointly
23 provided by both the Center for Seroepidemiologic
24 Studies, which will be at the Army Preventive

1 Medicine and Wellness Center, and by the Walter Reed
2 Army Institute of Research.

3 We expect the Preventive Medicine Center to
4 provide the administrative personnel and WRAIR to
5 provide the supporting effort needed for scientific
6 and research management issues. Hopefully uses of
7 the bank will rapidly expand to the point where it
8 can become to a significant extent self-supporting.

9 Thank you very much.

10 DR. KULLER: Do we have questions about the
11 bank? Russ.

12 DR. LUEPKER: Two questions. One, what do
13 feel for all costs of the bank for a year when you
14 factor in the contractor and the personnel you're
15 proposing, and second, a more scientific, technical
16 one. You've stored this at minus 25. What's lost
17 by doing that?

18 LIEUTENANT COLONEL KELLEY: For antibody,
19 there really isn't -- responding to your second
20 question first. For antibody, there really isn't a
21 problem at minus 25. There's a nice paper, which I
22 haven't committed to memory by Nicholas Petrakis, in
23 which he reviewed all of the -- the stability of all
24 sorts of components in sera and some of the ones

1 that don't do well, for example, at minus 25 are
2 some of the lipoproteins where it's preferable to
3 store them at minus 70. Certainly metals do well
4 at minus 25.

5 With respect to cost, the cost for the bank
6 as it stands now, that is the preservation of the 12
7 million specimens, the addition of one and a half
8 million specimens a year, and aliquoting, I think in
9 the budget we have aliquoting of 5,000 specimens a
10 year, comes up to just shy of a million dollars a
11 year.

12 The three personnel that are going to be
13 part of the Center for Seroepidemiologic Studies
14 might add several hundred thousand to that, and then
15 obviously, depending on the particular study you
16 want to do, there's a cost depending on how
17 intensive that is.

18 For example, the lymphoma program project
19 grant that I mentioned, over and above the structure
20 I've just outlined, is budgeted over four years at
21 about \$300,000 for the marginal costs of that
22 specific project.

23 DR. KULLER: It would seem to me that
24 this would be a valuable resource, but it needs

1 access. It seems to me that to maintain a resource
2 at this cost, you really need to get access to
3 national investigators who, one, can test specific
4 hypotheses and make the opening relatively simple.

5 One thing to consider, for example, is to
6 go the other way as to some of these diseases, is to
7 go back through the national death index and use the
8 national death index from NCHS as a way of
9 identifying deaths both, obviously, outside of the
10 service people who have left the service and a lot
11 of people with chronic illnesses may leave the
12 service and they'll be lost from your system or may
13 have developed a disease beyond the incubation
14 period where you're following them because they left
15 the service.

16 So that it would create, to some degree, a
17 potential problem. But I think you could use a
18 variety of different indices, State Cancer
19 registries, there are a lot of those available right
20 now who get cancer cases.

21 I think your repository's major focus is
22 going to be in serology and serology, both in terms
23 of inflammatory markers and in terms of viral or
24 other microbiological antibody titers, because at

1 minus at 20 degrees Centigrade, you've probably lost
2 the lipids and there is also, to be honest, there
3 isn't that much excitement unless somebody came
4 without looking at a genetic marker, in the lipid
5 area, that would probably be unexciting right now.

6 You could probably still look at
7 cholesterol, but probably couldn't get much beyond
8 that at minus 20 degrees. And looking at things
9 which are contaminated by the way the blood was
10 drawn, for example, metals would be pretty tough
11 because these were drawn in regular vials with
12 regular needles and so most of the metals you're
13 going to get are going to come from the
14 contamination of the blood drawing.

15 But certainly in the other areas, you have
16 a tremendous opportunity, especially in looking at
17 unique diseases in young people. And also, I don't
18 know how many women you have, but there are a lot of
19 very important diseases in young women where the
20 etiology is unknown, but the etiology is highly
21 suspected as either a viral or an etiological
22 disorder and where there would be some opportunity
23 to look prospectively.

24 But I think you have to come up with a

1 system that would make it possible for other
2 investigators, both within the government and by
3 that I mean people at NIH or other places, as well
4 as outside, to be able to utilize the repository and
5 to utilize it at a reasonable fee.

6 I'm not saying give it to them, but I'm
7 saying utilize it at a reasonable fee, so that if
8 you had ten or twenty studies going and they were
9 paying at least part of the tariff, at least on a
10 regular basis, at least you would have a way of
11 maintaining it, so it would be a shame to lose it.

12 The Navy, as you know, we're involved with
13 the Navy in a program which involves looking at
14 nature histo compatibility genes for the entire
15 Navy, using a new technique which has made it
16 possible to molecular level, to measure major histo
17 compatibility genes, which is being done as part of
18 this national bone marrow typing program.

19 And that resource, theoretically, could be
20 in some ways even linked with your serology battery
21 to give you an access, because we have cells to
22 access the DNA, to be able to look also at the
23 genetic components in relationship potentially to
24 both infectious diseases, but also to look at it

1 from infectious etiology or inflammatory etiology of
2 chronic diseases.

3 I think you really, in some ways, should
4 try to get the non military investigators who are
5 interested in seroepidemiology, as well as people at
6 NIH, to try to save this.

7 I would be very supportive and I think most
8 people at the Board, I presume, would be very, very
9 supportive of this need to save this repository and
10 not lose it, but there are a lot of sero
11 repositories in the United States which are just
12 that, they are repository and they remain that way
13 forever and nobody ever uses them.

14 We have one like that and expect for myself
15 and a few others, it's hardly ever used and it has a
16 lot, a lot of data -- a lot, a lot of serum, but
17 very little data.

18 LIEUTENANT COLONEL KELLEY: We have some
19 very specific ideas on how to proceed with the
20 exploitation of this. The biggest challenge, quite
21 frankly, and one thing we recently did is we
22 announced it in a broad mailing to about 200 to 300
23 civilian potential users, though we carefully said
24 we didn't want to solicit proposals yet.

1 And the reason why is I felt in my heart of
2 hearts that I didn't want to solicit proposals until
3 we could, in good faith, hold up our end of the
4 deal, because all of these studies would end up
5 being collaborative studies, since they depend
6 heavily on military data bases.

7 And without an infrastructure, the
8 infrastructure that we're moving to, there really
9 wasn't even ready access to people to do many
10 feasibility studies. That program project grants,
11 for example, people had to approach me, they had to
12 say how many lymphoma patients do you have?

13 Well, I couldn't just flip open a book and
14 figure out how many lymphoma patients we had and
15 then once I figured out how many we had, the
16 question was how many do you have sera on and how
17 many do you have sera on that predated the date of
18 their diagnosis?

19 Those sorts of feasibility studies take a
20 certain infrastructure to pull off. And then once
21 you've decided that you can collaborate, then
22 there's still many other steps even before you see a
23 nickel of money that might come in from a grant.

24 I think we're moving toward building that

1 infrastructure as I described, but that's been the
2 hold up right now.

3 DR. POLAND: I received one of those
4 letters and immediately drooled over the
5 possibilities, one, where you might frame this,
6 there is no large repository that I know of where
7 you can access large numbers of ethnic minorities
8 and in that letter, you made that point and I think
9 it's an excellent point worth making. There's a
10 crushing need for that.

11 The second things is as we go into the 21st
12 Century here, I recognize that it adds cost and some
13 legal and ethical complications, but storing cells,
14 I view as absolutely necessary. Without the genetic
15 data to link to the seroepidemiological studies that
16 you might do and think of for the future, it would
17 be a shame not to have them.

18 MS. STEVENS: I just wanted to raise a
19 sticky question that's come up in our setting. We
20 have a repository of samples that have been
21 collected since the late 60s from a variety of
22 different epidemiologic studies.

23 I just got confronted by an issue in a
24 study that we're setting up with the Department of

1 Health, where it was put to me, issues of consent.

2 Do we have consent for testing for things
3 that people didn't originally agree to be tested
4 for, keeping identifiers and linking the information
5 to identifiers, which is clearly a critical issue
6 for all of the kinds of studies that you are
7 thinking of proposing?

8 More recently, we have gotten consent sort
9 of for generic testing of things that might come up
10 in the future, but our experience recently with the
11 City Department of Health has gotten more sticky in
12 that they are saying now that this is not adequate,
13 that we have to now start making efforts to go back
14 to people to get consent for specific testing.

15 And not only that, if we find something
16 that is relevant to their health, make every effort
17 to try to inform people. I raise these issues more
18 or less almost with tears in my eyes, because I
19 think we're getting to a point where we're going to
20 be paralyzed in our ability to make really important
21 contributions from these different fields --

22 LIEUTENANT COLONEL KELLEY: There are a
23 lot of --

24 MS. STEVENS: -- but I don't know if these

1 are issues are coming up.

2 LIEUTENANT COLONEL KELLEY: That's an
3 issue that a lot of people are wrestling with. One
4 of the people I talked to is Geraldine McQuillian,
5 who some of you may know who is charge of the excess
6 Hanes sera, and they also have cells banked.

7 And some of these concerns that you're
8 mentioning have been brought up in that forum too
9 and they've come to the conclusion that if they went
10 to get explicit informed consent retrospectively,
11 which some say you should do, it would be \$2 million
12 added to every study, so it does prove to be a big
13 problem.

14 We have already addressed this with the
15 Judge Advocate General's office and I wouldn't
16 attempt to describe all of the machinations of how
17 this issue plays out. One of the things that has a
18 bearing is whether the sera was collected for a
19 military purpose in the first place, and that's why
20 it appears that -- it gets a little more complex
21 when you start using it for things that are not
22 military purposes.

23 If it's a valid military purpose, it's one
24 thing. If it's to study something that has nothing

1 to do with a military issue, it gets a little more
2 involved.

3 DR. KULLER: We, by the way, with
4 seroepidemiology, have been able to develop methods
5 which are fairly obvious that completely blind the
6 identification of the subject all the way through,
7 so that in a sense, the subject is not identified as
8 such and you can't link -- the only people who can
9 link the subject and the results of the test, are
10 the people who own the -- essentially own the
11 repository, so that the outside individuals,
12 somebody let's say sends you 300 -- I don't know
13 what the lymphomas -- but send you the lymphomas.

14 You can basically send serum back in which
15 you create your own blinded system for blinding both
16 the people and the serum and then they send you back
17 the results of the serological testing and then you
18 just feed them back the results that they need for
19 doing their stated analysis.

20 We do that now for purposes of keeping
21 ourselves blinded for bias, essentially, with
22 interpretation of data, but the people who request
23 the information never know who the individual person
24 is who essentially either had a positive or negative

1 test.

2 And so you can work out systems that will maintain
3 the system to be blind.

4 DR. ASCHER: The other trick we use in the
5 HIV newborn is that we create a data link and then,
6 before the fact, do the analysis and make sure that
7 no cell has less than five individuals in it. And
8 if there's a cell that has less than five
9 individuals, we start collapsing until the total
10 matrix of possible identifiers all contain more than
11 five.

12 And that then, is the link that is made if
13 the link is then broken. So you don't have to be
14 completely blind, as long as your probability of
15 ever being able to go back to the person after the
16 fact, is lessened and that works at some level, the
17 big note.

18 LIEUTENANT COLONEL PARKINSON: Now, I just
19 want to ask, you know, ultimately what you've got is
20 the perfect baseline for the post employment
21 surveillance, and I wonder if, in talking with Rick,
22 because he is going to be drafting at least a first
23 draft, along with ASDHA for what are the pieces we
24 need for the comprehensive post employment

1 surveillance.

2 And I think positioned in that regard, this
3 is the perfect -- if it's not a hundred percent of a
4 seral bank, you know, it's 75 or 80 percent of the
5 population you need and it represents the true pre-
6 exposure to the military service baseline.

7 And in that regard, a million dollars is
8 chicken feed. I mean, we just heard we're going to
9 be spending nearly that every year for three
10 epidemiologic studies over the next four to five
11 years and I think if it got positioned as part of
12 that comprehensive DOD effort to do surveillance and
13 the lookback program, that the million dollars could
14 be found perhaps more expeditiously than it is as
15 part of an HIV research program and I'd be glad to
16 work for it.

17 DR. CIRONE: That has been discussed and
18 they've talked with Dr. Boswell from WRAIR and
19 Captain St. Andre, not only for the Gulf War, but
20 for Somalia and we have discussed this before about
21 what do we do in the future and how can we look to
22 other wars that might break out or times when we may
23 deploy troops, what would be the best way to
24 approach it so that we can learn some lessons.

1 So that has been discussed and we are
2 currently discussing it. I don't know if they've
3 come to any conclusions on exactly how we're going
4 to do it.

5 The other thing is institutional review
6 boards, who normally review protocols and they'll be
7 taking a look at, you know, is it a blind study, is
8 it not a blind study.

9 You know, you're going to go back and
10 before you get involved if it's a military -- and
11 certainly that will go back to the question of
12 informed consent, et cetera.

13 LIEUTENANT COLONEL KELLEY: Right, and we
14 have -- the studies that have been completed have
15 been, if they were considered research studies and
16 many of them were, did go through the appropriate
17 human use review boards before.

18 VOICE: I'm just curious. Could you
19 explain why there's no Air Force people in that --

20 LIEUTENANT COLONEL KELLEY: I know no
21 better the history of how that happened. We do have
22 the sera on the Air Force recruit applicants, so
23 it's not a total loss.

24 LIEUTENANT COLONEL PARKINSON: And we

1 maintain some sera that come through Lackland
2 because basically -- mainly through our blood
3 donation programs, so we have a source down there,
4 all of which has to be factored into this
5 comprehensive DOD surveillance, if we're going to do
6 it.

7 VOICE: Do you, given the estimate of what
8 proportion of the sera is from individuals who are
9 now discharged from the service and if you keep it
10 on applicants, does that mean you have sera
11 individuals who never entered the service, that
12 decided not to become applicants?

13 LIEUTENANT COLONEL KELLEY: That's right.
14 And I don't have a precise figure for what
15 percentage are no longer in.

16 I wouldn't be surprised if half the people
17 or even three-quarters of the people in there aren't
18 in at the moment.

19 MR. RUSSELL: But for individuals who have
20 come in and stayed in, you would have multiple sets.

21 LIEUTENANT COLONEL KELLEY: That's
22 correct, that's correct.

23 Right. And in general in the Army, you're
24 getting blood every two years, some more frequently

1 than that.

2 DR. KULLER: Last question.

3 DR. MULLICK: I want to underscore what
4 three other people have said, that there's certainly
5 a very valuable, and both an operational and
6 clinical uses for this repository.

7 Also, it certainly looks like we are going
8 to be increasing our surveillance. There have been
9 suggestions that every serviceman who deploys
10 overseas, which is thousands and thousands of
11 soldiers
12 annually, if that indeed can be used as a pre-
13 deployment sera.

14 And I think it certainly could since,
15 certainly the Army, every soldier contributes every
16 two years; Navy every one year or every two years
17 and that would be cheap, rather than having to draw
18 blood on all of these individuals who are deploying
19 from mini bases, from mini ships.

20 And I think that is something that the
21 services may want to ask the Board for, is support
22 in -- if money is needed to keep this going until
23 the overall DOD surveillance plan is put into place.

24

1 But the plan, if it goes into place and
2 Colonel Erickman has started work on it as the
3 Chairman of the group to work on that, I think it's
4 going to be expensive.

5 It's not going to be cheap to put into
6 place what the services are going to be asked to do,
7 but this is a place that could really save money.

8 LIEUTENANT COLONEL KELLEY: Thank you.

9 DR. KULLER: Thank you very much. That was
10 very good.

11 LIEUTENANT COLONEL KELLEY: Thank you.

12 DR. KULLER: We have a couple of
13 announcements.

14 COLONEL PETERSON: Directions to the
15 restaurant from this location will be on the table
16 outside the door and if anybody wants to volunteer
17 and raise their hand, who knows how to get there,
18 we'll all follow that one person and get out there.
19

20 Otherwise, we're depending on the
21 directions.

22 Tomorrow we're scheduled to start at 7:30,
23 just to make sure everybody knows the time is
24 different than what it was this morning.

1 I understand that we can leave items here
2 in the room, but they should not be personal items
3 such as briefcases. Leave paperwork and things like
4 that because there's a cleaning crew that comes in
5 here and that's all I have.

6 DR. KULLER: I have one message for the
7 Board that if at all possible, we would like to
8 briefly meet at -- is everybody staying at the
9 hotel?

10 Is anybody not staying? We'd like to
11 briefly meet at the hotel tonight after we get back.

12

13 It should be around 9:30 for maybe 30
14 minutes if we could.

15 That would be about the best time to go
16 over a couple of rather critical issues and some
17 memorandum if we can do it tonight.

18 Either that or if we can't do it tonight,
19 then we'll have to do it tomorrow morning
20 at 7:00, because the meeting starts here at 7:30.

21 So tonight or tomorrow morning.

22 Okay, but any way, we'll try to do it
23 tonight.

24 (Whereupon, at 5:20 o'clock p.m., the

1 meeting was adjourned, to reconvene on Friday, July
2 8th, 1994, at 7:30 o'clock a.m., in the same place.)

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